EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
MASTER FILE NO: 2:12-MD-02327

MDL 2327

IN RE: JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

ETHICON, INC., PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

DEPOSITION OF PETER JEPPSON, MD, FACOG, FACS

May 16, 2019
9:30 a.m.
500 Fourth Street NW, Suite 1000
Albuquerque, New Mexico 87102

This deposition was taken by:
BRAD BRADFORD, ESQ.
ATTORNEY FOR PLAINTIFFS

REPORTED BY: DANA N. SREBRENICK, CRR, CLR
NM CCR #513
GOLKOW LITIGATION SERVICES
877.370.DEPS

Page 5

PETER JEPPSON, MD, FACOG, FACS
after having been first duly sworn under oath, was questioned and testified as follows:
EXAMINATION BY MR. BRADFORD:
Q. Good morning, Dr. Jeppson.
A. Hello. Good morning.
Q. I'm going to be asking you some questions today about an expert report that you filed in the Ethicon transvaginal mesh litigation, okay?
A. Okay.
Q. And also about the materials that you reviewed and your background and experience and kind of what led you to being here today and what led you to the experience to issue the reports you rendered, okay?
A. Okay.
Q. I know you've been deposed at least once before in this litigation -- and by "this litigation," I mean the transvaginal mesh litigation -- is that correct?
A. Yes, sir.
Q. All right. And I don't want to -- I'm sure your counsel has gone over this with you. I don't want to waste a lot of time on the ground rules, but the basic ones are, if you don't

Page 6

understand my question, let me know, and I'll ask it better or differently, okay?
A. Okay.
Q. Is that fair?
A. Yes.
Q. And if you answer my question, is it fair that you understood it?
A. Yes.
Q. I want to start -- we got a lot of materials here today, and I'll start by marking the Notice of Deposition in this case as the next exhibit.
(Exhibit T-1, Notice of Deposition, marked for identification.)
BY MR. BRADFORD:
Q. All right. Doctor, we marked as Exhibit T-1 to your deposition the Notice of Deposition that we filed in this case.
Have you seen this document before?
A. Yes.
Q. All right. You've got some boxes and some, it looks like, printed materials and a thumb drive in front of you. I'm assuming those are responsive to the portion of the notice that is the Schedule A; is that correct?

Page 7

A. Yes, sir.
Q. All right. I don't know if between you or between you and counsel -- I really don't care -- whatever the easiest way is, tell me what you got here today.
A. So essentially I brought correspondence between me and counsel, and then I have an invoice for the time spent on the general reports for both of them. And then I have the reports that I wrote along with the supporting documents for those, and then I have materials that were referenced, general materials, relating to mesh use.
Q. Okay. So what's on the thumb drive?
A. So the thumb drive is essentially information that's on the -- in the binders.
MR. KOOPMANN: Well, let me clarify. The thumb drive contains all the general materials he's been sent throughout his involvement in the litigation.
The binders contain his -- his sacrocolpopexy report and his midurethral sling report and the materials that he sited in those reports. So the thumb drive contains more than the binders technically.

Page 8

BY MR. BRADFORD:
Q. All right. So the binders and their -- or, several of these are floating around. How many binders did you bring -- how many original blinders, not including copies, do you have?
A. Four. They are all about the same size, and they're --
Q. I don't need them up here, I don't think. So just so I understand correctly, the thumb drive contains everything provided to you by Ethicon to review -- Ethicon's counsel or Ethicon to review in forming your opinions; is that correct?
A. No, that's not correct. This includes the information that I was sent by them as well as the information that I reviewed. It does not include all the information that I've reviewed relating to mesh or mesh use.
That would be in the last, you know, 15 years' worth of information that I've read and studied and learned from, you know, medical school, residency, fellowship, national meetings, articles that I've written and then literature that I've kept up with both for maintenance of certification as well as just general knowledge to practice as a urogynecologist.

Page 9

Q. I'm going to mark as T-2 your reliance list that was provided to us in this case.
(Exhibit T-2, Reliance list, marked for identification.)
MR. KOOPMANN: And, counsel, for clarification, I don't know if I made this clear, but this binder contains a sacrocolpopexy report and the materials cited in that. This contains his midurethral sling report. And then the other two binders are just miscellaneous documents, internal documents, deposition transcripts, things like that.
MR. BRADFORD: Okay. Thank you.
BY MR. BRADFORD:
Q. All right, Dr. Jeppson, you've got marked the reliance list that was provided to us by Ethicon as Exhibit T-2. What I'm trying to do -- I'm not trying to trick you. I'm not -- you know, I'm just trying to figure out what you have here today versus the materials that are on your reliance list, okay?
And I know separate and different from that is your experience in medical school and residency and reading literature and whatever else -- whatever other experience you have, okay?

Page 10

So I appreciate that's separate and distinct, but for right now, I want to focus on the reliance list, your reports and what you have in front of you, okay?
A. Okay.
Q. All right. So, for example, the binder I'm looking at now contains your sacrocolpopexy report, correct?
A. That is correct.
Q. Okay. And does it also contain the references you've cited in the footnotes or in the text of your report?
A. That is correct. That is what is in that binder is the report that I wrote and the supporting documents to go along with this.
MR. BRADFORD: I'm going to go ahead and mark this binder as T-3.
(Exhibit T-3, Binder containing sacrocolpopexy report, marked for identification.)
BY MR. BRADFORD:
Q. All right. There's another binder that's in front of you that contains your general report for the slings you're here to testify on in this case, meaning the TVT, the TVT-O and the TVT Abbrevo, correct?

Page 11

A. That is correct.
Q. And also are -- the attachments are the other tabbed exhibits to this binder. Is that the materials referenced and cited within your report, either footnotes or in the report itself?
A. That is correct.
Q. Okay. I'm going to mark this as T-4, please.
(Exhibit T-4, Binder containing general report for slings, marked for identification.)
BY MR. BRADFORD:
Q. Okay. And there are two more binders you brought, correct?
A. Yes.
Q. Maybe you can slide these out of the way for now. And I will mark these T-5 and T-6. And they're titled SUI Mesh Documents Binder 1. I'll mark that as T-5.
(Exhibit T-5, SUI Mesh Documents Binder 1, marked for identification.)
BY MR. BRADFORD:
Q. And then SUI Mesh Documents Binder 2, I'll mark as T-6.
(Exhibit T-6, SUI Mesh Documents Binder 2, marked for identification.)

Page 12

BY MR. BRADFORD:
Q. All right, Dr. Jeppson, if you look at what we've marked now as Exhibit T-2, which is your reliance list -- it's over here.
A. Uh-huh.
Q. -- it's a -- I'm not going to guess how many pages, but it's a many page document that includes lots of medical literature, correct?
A. That is correct.
Q. And then it also -- after the medical literature is -- strike that.
There's an alphabetized list of medical literature, correct?
A. Yes.
Q. All right. And then after that there is a section called Production Materials which includes some general things including what looks to be Ethicon internal documents?
A. Yes, that is correct.
Q. All right. And then after that is included a section called Company Witness Depositions, correct?
A. Yes.
Q. And then there's a section titled Other Materials, correct?

Page 13

A. Yes, that is correct.
Q. Okay. Everything included in T-2, which is your reliance list, can't be included in these two binders, right?
A. Cannot be?
Q. It's not. I mean, it's -- these binders don't constitute everything that was included in your reliance list?
A. That is correct. These are what support the documents here, but is not everything in the reliance list.
Q. If they did, there would be binders to the ceiling many times over, I suspect?
A. Yes. They would be very big binders, yes.
Q. Tell me, what is significant about what is in T-5 and 6 versus the other materials listed on the reliance list? Why are these here as opposed to all this stuff?
A. From my perspective, when I write a report, it's very similar to when I would write and submit a manuscript for publication, so I am not just purporting my opinions. I am purporting that the evidence that is available and the evidence to support the statements that I'm

Page 14

making. And so the reason or the rationale to have binders with references is so that, as you read the report, you can see what was referenced in making -- in making -- in drafting the report and what supports those statements.
Q. The actual citations themselves and the studies or materials that are actually cited within your report are included in the binders with the report, correct?
A. That you have in front of you, yes.
MR. KOOPMANN: Those are just my copies of those.
MR. BRADFORD: Maybe I'm confused.
BY MR. BRADFORD:
Q. So if you look at your report, you have citations and footnotes within your report; is that right?
A. That is correct.
Q. And that is what is included in the binder with your report, fair?
A. That is what you have in front of you, yes. This is the report. This is the binder with the -- well, I'm sorry. These are different. I moved it down. I apologize. I thought you still had the SUI and the colpopexy reports in front of

Page 15

you.
Q. Okay. Let me start over because I've exchanged those binders, and they're now out of the way. And these are two additional binders, correct?
A. These are general materials, yes.
Q. And as I asked you before, these two binders do not contain everything that is in the reliance list that was provided to us by Ethicon, correct?
A. Yes.
Q. What is significant about these documents that caused you to bring them separately today as opposed to all the other stuff in the reliance list?
A. So these are materials that I reviewed as I became an expert witness for -- for Ethicon. These are the documents that I went through that were -- are perhaps slightly more important, or they needed to be reviewed to ensure that I went through all of them.
Again, as you mentioned, there is so much data available. It's not possible to incorporate it all. And so your question as to why these are more important, you know, again, these are

Page 16

documents that I think are necessary to be known as an expert witness, but are not necessarily the most important in forming medical opinions, if that makes sense.
Internal documents from Johnson & Johnson and whatnot are not readily available in the medical literature and that sort of thing, so these were provided to me for review.
Q. Looking back to T-1, which is the Notice of Deposition, I want to look over to Schedule A, and I'm not going to ask about each of these things. I've got a lot of -- a lot of these have been produced, but I do have questions about a few of them.
You have in front of you, it looks like, some billing records and then some correspondence, including the work surrounding the billing; is that correct?
A. Yes.
Q. Can I see those, please?
A. Yes.
Q. These weren't in any particular order; were they?
A. No.
MR. KOOPMANN: I don't think so.

Page 17

BY MR. BRADFORD:
Q. I didn't want to reorder them and do anything that you wouldn't like. I'm going to mark as T-7 an invoice that you brought with you today, and hopefully we can look at this together.
(Exhibit T-7, Invoice, marked for identification.)
BY MR. BRADFORD:
Q. All right, Dr. Jeppson, looking at what we marked as T-7, that is your -- it looks like a billing invoice; is that correct?
A. Yes, sir.
Q. All right. And looking at -- there's no date itemization on this; is that correct?
A. That is correct.
Q. It's just a -- there's a gross -- a number of hours and then your rate for what is described as the MUS general report and the colpopexy general report, correct?
A. That is correct.
Q. All right. And from what date range does this billing encompass? And let me -- before I do that, the date of the invoice is May 15th of '19?
A. Yes.
Q. That is yesterday, correct?

Page 18

A. That is correct.
Q. Okay. From what time frame generally? I'm not going to marry -- if you miss it by a month, I don't care. I'm just looking for when did you start for this billing invoice, and when did you stop?
A. I honestly don't remember when I started. It's probably been five or six months is my guess. There was a request to generate a report, and as I've worked on that, I've just kept the time as a lump sum. I haven't itemized the time, as you mentioned.
I did not keep track of the time in an itemized form, but as I was reviewing materials specific to the report and as I was drafting the report and as I was preparing for this deposition, all of that time is lumped into, you know -- into that time, but, you know, a ballpark, you know, six months.
Q. All right. And how current is this report, meaning through when is this -- the invoice marked as T-7 accurate?
A. I updated it last night which is why it's dated the 15th. I will update it again at the conclusion of today's proceedings and then submit

Page 19

it to Johnson & Johnson.
Q. Is your rate different for a deposition than record review or for preparation?
A. It is not. I have a standard rate.
Q. I will next mark as Exhibit T-8 a letter that -- in the group of documents you provided. It's a letter from Bowman and Brooke. It looks to be signed by Mr. Koopmann, correct?
A. Yes.
Q. And that's the gentleman sitting next to you today from Ethicon who is your counsel?
A. Yes, sir.
MR. KOOPMANN: Objection. I'm -- I'm J&J's and Ethicon's counsel, not his counsel, but...
THE WITNESS: Yeah.
MR. BRADFORD: Fair enough.
We're going to mark that.
(Exhibit T-8, Letter from Bowman and Brooke signed by Mr. Koopmann to Dr. Jeppson, dated April 19, 2018, marked for identification.)
BY MR. BRADFORD:
Q. All right, Dr. Jeppson, I've marked as Exhibit 8 a letter to you from Mr. Koopmann from Bowman and Brooke dated April 19, 2018.

Page 20

Are you familiar with this document?
A. Yes.
Q. All right. In my quick review of these documents that you provided regarding your billing, that's the earliest dated one being back in April of 2018.
Do you recall when you were first approached by Mr. Koopmann or Ethicon or anyone else to work as an expert in this transvaginal mesh litigation?
A. It would have been close to that time, but I don't remember for sure.
Q. And I'm not -- again, I don't care about a week or even a month's difference, but close to that time, what's the best you can give me as to when you would have been first contacted?
A. It would have been probably within a month or two of the signed document.
Q. And how were you first contracted to work as a potential expert for Ethicon in this litigation?
A. Mr. Koopmann contacted me through my institution, and I replied that I would be interested in being an expert witness for Ethicon.
Q. You referenced through your institution.

Page 21

What do you mean?
A. I work for the University of New Mexico. The administrative assistant that worked for me at the time received a message that she forwarded to me, and I replied to them.
Q. I'm going to mark the rest of these documents, the correspondences surrounding the billing that you provided as just a composite, as T-9.
(Exhibit T-9, Correspondence surrounding billing, marked for identification.)
BY MR. BRADFORD:
Q. I'm going to clip these together with paperclips, so they stay together the best they can. I don't think I'm going to ask any general questions about these, right now anyways.
Do you have any other documents that would reflect or reference any of your billing for your work for Ethicon in this matter?
A. No, I don't.
Q. Have you ever worked as a consultant for Ethicon outside of serving as a testifying expert in the transvaginal mesh litigation?
A. I have not.
Q. Are you familiar with the term "key

Page 22

opinion leader"?
A. Yes. I've heard that term as it relates to federal funding, stakeholders and key opinion holders, yes.
Q. Do you have any contracts with Ethicon to work -- to do any consulting for them outside of this litigation?
A. I do not have any contracts with any -- with any businesses or, you know, medical -- anything outside of this.
Q. Okay. I was going to lead into those questions. So have you ever worked as a key opinion leader for Ethicon?
A. No, I have not.
Q. Have you ever taught courses for Ethicon products on Ethicon's behalf?
A. I have taught courses, but never for Ethicon. I've done them through national or international organizations, but never for Ethicon.
Q. Have you ever been paid by Ethicon to speak on its behalf?
A. I have not.
Q. Have you ever been paid by Ethicon to present to doctors regarding its products?

Page 23

A. I have not.
Q. Have you ever been paid by Ethicon for anything other than your work in this litigation?
A. I have not.
Q. I want to ask you the same questions for other manufacturers or industry entities, if you understand what I mean.
A. Yes. I have never received payment from industry in any other regard. As an institution, as part of our group, we do research studies, some of which are funded by industry, but the funding would come to the institution to provide support for the -- the research assistance in those types of things, not directly to any of us. And I am not the primary on any of those grants, if you will.
Q. And are those grants -- I've been through your CV that you provided for us. Are those grants and that information included within your CV?
A. Anything that I've been involved in are included in my CV, and there is a section of grants.
Q. Okay. Thank you, Doctor. We'll get there in a minute.

Page 24

You're saving some time this morning.
A. I am?
Q. You are.
I want to direct you to what was marked as Exhibit T-2. That's the reliance list again. I think I'm actually going to be finished with this one. I'll put this in the pile over here, okay?
A. Okay.
Q. Okay. I want to go through the reliance list, not item by item, but -- Lord knows we don't have the time, but I want to go through there and just talk about what you've reviewed, what you've reviewed thoroughly, what you might have skimmed, what you would not have looked at, if any, okay? And I don't want to do this item by item certainly, but, I mean, we can if we need to.
As far as the studies listed, the medical literature as described by Ethicon, did you prepare this list?
A. I did not prepare the list.
Q. Was this list provided to you by Ethicon?
A. Someone within Ethicon compiled the list that, provided that this list was given to me, so if that's what you mean by provided. They did not

Page 25

generate the list and say, This is what we want you to go through. They provided some information particularly towards the back as you kind of went through earlier, you know, and some of the production materials, some of the company witness depositions. Those types of things I would not have had access to, but the medical literature, I mean, it's all available through Medline.
And so much of this information and really essentially everything in my report -- in my reports, pleural, you know, is information that I'm aware of or that I've read or that I've seen elsewhere. I did go through the -- I went through this material again, some in more depth than others, but as a practicing urogynecologist, this information is very pertinent to my day-to-day patient interaction treatment algorithms.
So the medical literature is, in general, generality, is information that I was aware of or that I found as I was searching, but much of it is information that I'm aware of, if that makes sense.
Q. Sure. And we'll go through -- I'm going to go through your background and experience in more detail in a little bit, but is it fair to say

Page 26

that you work at a teaching hospital?
A. Yes, sir.
Q. And as part of working at a teaching hospital, you teach residents; is that correct?
A. I'm hired through the School of Medicine. I have an appointment with the School of Medicine for medical students. I often teach students in clinical settings and in classroom settings. I also teach the residents as they rotate through our service, both formally as well as informally and in rounds in the OR and that type of thing.
We also have a fellowship. I am very engaged with the fellowship teaching as I am with the others. We just had meetings this morning. We had didactics from 7:00 to 8:00, and then another didactics meeting from 8:00 to 9:00, and that's our -- my typical Thursday morning are division meetings with didactics for the learners.
Q. I'd expect you have interest outside of medicine also?
A. Certainly.
Q. All right. I want to just ask you generally, tell me about whether you can describe for me, whether it's by the week or the month or whatever is easiest, Dr. Jeppson, but tell me

Page 27

generally about your -- the time you spend working and what you do. I can ask smaller bites if you would like.
A. No, that's fine.
As a general rule, I am -- I very much like my job. I enjoy what I do. I like seeing patients and treating my patients. As a practicing physician, I have a busy clinical schedule. I'm in the OR every Monday. I'm in clinics on Tuesdays and Wednesdays. I have some med student teaching obligations on Tuesday afternoons. Wednesday is all day clinic. Thursday, I have some clinical responsibilities on Thursdays. We have the didactic sessions I already discussed on Thursdays.
Fridays are grand rounds, and Friday for me tends to be more administrative time. I am the chief of the division of urogynecology. I get a couple hundred e-mails a day that I keep up with. I, you know, get all the medical results, all that stuff, for patient care as well that I keep up with.
On a given day, I would typically wake up around 5:00 -- between 5:00 and 6:00 a.m. I tend to go through e-mail in the morning. Sometimes

Page 28

I'll take my dog for a walk. Go to work through the day. Come home at night. I'm usually home by 6:00-ish. I have dinner with my family. My boys are involved in baseball and other activities like that that I go to.
Once we get the kids in bed around 8:30 or 9:00 and we've done homework and all of that, I talk to my wife for a bit, and then I get back to the e-mail and the research projects that I'm involved in, and that tends to be until 10:00 o'clock or so.
Weekends I, again, tend to get up early. I wake up without an alarm around 5:00 or 6:00. Work on things until 7:00 or 8:00 when my boys get up, and then I try not to do much on Saturdays or Sundays aside from, you know, non -- I don't want to take away from family time. That sometimes is necessary. I do have an occasional call that, you know, I cover at the hospital, but that is more or less my general schedule.
Q. Thank you, Doctor, and congratulations on your balance. That's important. So I've seen that you've written a lot on that, and that's important, so as your career goes along, keep that up. Be sure to keep up your balance, okay?

Page 29

A. Thank you.
Q. How many hours a week do you spend in clinic, and how many patients per hours in a week do you see?
A. I -- my FTE, which is the full-time equivalent clinic, I think is .55. I usually work around .6 or .65 clinical. That includes OR and clinic. I exceed the institution's expectations of me as far as clinical goes, but I prefer to be above than under on anything.
As far as patients per half day, it varies. Depends on, you know, who comes to clinic, no show rates and that sort of thing, which patients come to clinic and which don't. You know, I have clinics where maybe, you know, three or four people show up, which is unusual. Typical would be probably somewhere around eight per half day, six to eight. And then the other would be clinics where things get overbooked, and I'm seeing, you know, 14 to 17 per half day. It just depends on the day.
Q. Sure. And Monday's your operating day?
A. I'm in the OR on Mondays, occasionally on Tuesdays.
Q. Okay. How many cases on average do you

Page 30

do weekly or monthly, whatever is the easiest way for you to describe it?

A. It depends on if they're majors or minors. Typically I would do somewhere between probably three to five surgeries on a given OR day, again, depending on the length and the complexity of the case.

You know, very complicated cases, there might only be two. I don't -- I mean, I have all that information available, but I don't remember it off the top of my head.

We do go through our metrics as a division monthly. Our monthly metrics meeting will be next Thursday, and so I do look at all that. And as division director, you know, I think it's my job to know how the division is doing, but I don't keep all those numbers in my head. There's too much to remember and so...

Q. Thank you, Doctor. And general is fine. You know, I'm not -- again, if it's a higher or lower number within a margin, that's not of significance to me. I mean, you're welcome to look at that and supplement this answer when the time comes if you would like, but I'm pleased -- you know, I'm okay with the general nature of what

Page 31

you're telling me.

I want to talk to you about your teaching, and for this question, it's not in the clinic necessarily. I'm talking about classroom teaching, okay?

How much time do you spend per week on average doing that?

A. I don't know. As I mentioned, we have didactic sessions every Thursday. That's going to be at least an hour, if not two. I teach -- I used to be the residency, the assistant program director, and as that, one of my job was to coordinate and essentially arrange all of the resident teaching.

So I did that for two years, and so, you know, that would be three hours every Friday morning. That wasn't always me directly, but it was me coordinating, you know, and following the -- the ABOG, learning objectives for the residents to make sure they were getting the full gamut or the full representation of what was needed for their license exams.

For the residents, it's similar. I am not the program director of the fellowship, but as division chief, I am very involved in the

Page 32

fellowship, and I do review that with the fellowship and the assistant fellowship directors in making sure that we're covering the information pertinent to trainees in female pelvic medicine and reconstructive surgery, female pelvic medicine and reconstructive surgery, which is what urogynecology is.

The name through the American Board of Obstetrician and Gynecology, which is ABOG, is FPMRS, the female pelvic medicine reconstructive surgery, but urogyn is what it's called, you know, by most people. So, you know, it's hard for me to break down and say how much in classroom. Classroom on a given week is probably going to be at least -- at least two hours, you know, quote, unquote, classroom time and in meetings, grand rounds, all that kind of stuff, yeah.

Q. And how much time on average weekly do you spend with -- in the fellowship with the fellows or the residents in clinic or the OR or whatever more, not didactic, but hands-on?

A. I think he asked me how much time I spend with the residents and fellows in clinical and operating settings.

Q. I used the word "didactic."

Page 33

A. Didactic, yeah.

So it's unusual for me not to have learners with me in those settings. In the operating room, I typically would have a medical student, a resident and a fellow, so it's going to be every Monday. Tuesday, my Tuesday clinic I have a resident with me. The Wednesday clinic I usually have a student with me in the morning and a fellow with me in the afternoon is more or less the breakdown.

Q. How much time per week or per month do you spend reviewing medical literature?

A. A lot, but I mean, I -- I'm constantly reading. I mean, I -- part of getting up early in the morning is keeping up with literature. I get e-mails from JAMA and from other, you know, large journals.

I'm a member of AUGS. AUGS sends out a weekly e-mail with articles of interest. As part of our fellowship didactics, primarily we tend to have journal club at least every other week, if not more often, which will consist of one or two journal articles.

For patient care, I will look things up specific to patients as well as needed, and then I

Page 34

have been very involved in research projects and many of which are systematic reviews. And so, I mean, systematic reviews, you're taking a topic and reading essentially everything on that topic to coalesce or condensate the information into a report.

And as you'll see from my CV, I have several systematic review publications. I have several that are ongoing. I mean, a lot, I read a lot.

Q. You had mentioned AUGS, and which -- strike that.

Which medical journals do you routinely review?

A. Oh, I get The Green Journal, which is Obstetrician & Gynecology. I get The Gray Journal, which is the American Journal of Obstetrics & Gynecology. Those both come to me in print. I also get The Yellow Journal, which is the Female Pelvic Medicine & Reconstructive Surgery journal. That's the one from AUGS. The Green is from ACOG.

You know, I look at stuff, and I'm also a member of the American College of Surgeons. I get their journals online. I skim through the topics

Page 35

to see if there would be things of interest to me as a surgeon, a Journal of Urology in urology as well as the New England Journal, JAMA. I mean, these are things that come to me in e-mail form or in other kinds of consolidated form to help identify what would be of interest. I mean, I get a lot.

Q. Looking back to the reliance list, I want to go through and be sure I understand what you've looked at and what you haven't.

So just so I'm clear, you did not type this list up, correct?

A. That is correct, I did not type this list up. I did not compile it.

Q. And this list regarding the medical literature on Exhibit T-2 was compiled by someone with Ethicon, correct?

A. Yeah. I'm assuming a paralegal or someone like that. I don't know who.

Q. And they provided you this list, correct?

A. They compiled the list and provided it to me, yes.

Q. Did they provide all of the articles contained within the alphabetical list of medical literature to you?

Page 36

A. So if you're asking if they gave me this list and told me to include it, the answer is no. If you're asking if they compiled this list and printed and collated and put everything in the binders, then, yes.

Do you understand the distinction?

Q. I do understand it. I'm asking not to what they told you to put in your report. I'm not going there at all. I'm not inferring that.

I'm asking specifically for these questions what they did and what you received from them.

A. Correct. They compiled the list and compiled the printed documents to go along with the list for the report.

Q. And when you point to those, you're pointing to the binders marked Exhibits T --

MS. BAGGETT: 5 and 6.

BY MR. BRADFORD:

Q. -- 3 through 6?

A. Yes.

Q. Did they provide you a copy of all of the medical literature in this reliance list, whether it be binders like that, whether it be via Dropbox, e-mail, hard drive, thumb drive?

Page 37

Were you provided all of the medical literature in -- listed on the reliance list by Ethicon?

A. I'm not sure if I understand the question. Are you asking me if I was given everything by them to review?

Q. I'm asking if every piece of medical literature in this reliance list was provided to you by Ethicon, whether hard copy, digital copy, on a drive, however.

A. So it may be semantics. Some of this information I provided to them to include, which then they gave back to me, but the information that's in the reliance list is information that I have received. And I think all of it is on the thumb drive or in some other form.

Q. The question is simpler. I'm not trying to get in the weeds with you or infer anything. What I'm trying to just see is, did Ethicon provide you either a hard digital or copy in some other form of everything on the reliance list listed under Medical Literature?

A. I believe everything on the reliance list is on the thumb drive.

Q. Okay. And that was prepared to give to

Page 38

me today, correct?
A. This is a copy to submit, yes.
Q. How did they give it to you?
A. So I have the information in the binders that was reviewed. Some came via e-mail. I think those are in the e-mail list that was seen. You know, much of that, I don't remember if it was all sent secure. I know anything patient is sent secure, that I have to login and download, but I think many of those were as well.
And then the thumb drive is here. It was brought today specific for this. I have a copy of the thumb drive as well. And then there's the list here. So perhaps I'm not understanding the question because I feel like I'm answering it, but then you re-ask, so maybe I'm missing something.
Q. Is every study or article listed under Medical Literature on the reliance list on this thumb drive?
A. Yes.
Q. And before today or whenever this was copied to give to me, Ethicon had provided all of that to you?
A. Yes, with the caveats that we've gone through, yes. It was information that I received

Page 39

from Ethicon, and again, I might -- I might not be understanding, so please forgive me if I'm not, but, you know, again, I -- you know, it's not like Ethicon just gave me this stuff and said, Here, you know, look at all this stuff.
It's -- you know, some of that is true, but much of this, particularly the medical literature, is stuff that I've already known or seen or coauthored, all right, and so I did not receive that from Ethicon. Like, I already knew about that.
Does that make sense?
Q. Yes. Is all of the medical literature significant to your opinions in this case contained within those four binders?
A. I would say no, not pertaining to mesh. It's impossible to put everything that would be important in a given binder. I mean, it's -- I mean, textbooks and I mean -- I mean, the amount of medical literature out there is immense, you know.
This is information pertinent to the reports and pertinent to the discussion, but I don't think that it contains everything. I don't think it's possible to contain everything in a

Page 40

printed form.
And then certainly, you know, experience from treating patients and that sort of stuff doesn't -- I mean, that stuff doesn't get printed and go in here, but I have a lot of experience with patients, and it does determine how you treat.
So -- but, again, please feel free to re-ask if I'm not understanding.
Q. Yeah, sure. Specifically, as to the medical literature -- and here's the deal, right? This is my chance to talk to you.
A. Yeah.
Q. This is my chance to learn the basis and foundation for your opinions and what those opinions are, right?
What I want to do is I want to be sure I have the opportunity to look at, as opposed to hundreds and hundreds and hundreds of studies or pieces of journal literature, some of which are meaningless to you in your opinions, I want to look at what is meaningful, so when the time comes, either me or some other lawyer around this country can look at the relevant materials to ask you questions about it, okay?

Page 41

That's the purpose of my question now.
A. Okay.
Q. And that's why I'm asking. And I would really not -- I just as soon not go through each of these. I mean, I can, and I don't want to.
A. I don't want to either --
Q. Okay.
A. -- but I feel like I'm answering the question, so that's where I'm struggling.
Like, is this information important to the discussion? Yes, that's why it's here.
Q. Is every study or journal article listed under the Medical Literature portion important to your opinions in this case?
A. So everything listed here is important. I guess, you know, the -- the stuff that I sign, and if you look at the contract -- I think it's in there -- you know, and then certainly whenever I -- you know, it's, you know, based on my -- my current knowledge which can change based on future publications, right?
I mean, if you're asking me if all of these studies are weighted the same, the answer is no. Systematic reviews, randomized controlled trials are going to be much higher evidence than

Page 42

some case series. This includes a lot of different information.

When looking at medical literature, some information is better obtained from case series and from these kind of less well designed studies. Things like adverse events and those kinds of things typically are not well represented in a randomized controlled trial.

A randomized controlled trial might only have 20 patients per arm, and so you're only looking at a total of 40 patients, whereas you can get essentially a case series or a population based study out of Scandinavia with 20 patients. But you can get population based studies that would have a huge number of patients that it would be more important to me as I make opinions regarding adverse events.

So does that -- again, I feel like I'm not understanding the question. Are the things in here important? Yes, I think they are important, or they wouldn't be included. Do I think that these are the most important? Well, I think that these are important studies that we should discuss.

I agree, I don't want to go itemized line

Page 43

by line. I don't want to do that. But, you know, if there's a study of ten patients on a given topic, that might be important for that one point, but not important to everything. It's a composite. That's how medicine is practiced. I feel like I'm missing the -- I don't understand.

Q. I mean, certainly I'm going to have some questions later about, you know, level 1 data and the difference between randomized controlled trials and, you know -- and other case reports and smaller studies. We'll talk about the significance of that later, and I understand that.

Let me ask this: Have you read every study listed under the Medical Literature portion of the reliance list?

A. I have certainly referenced all of them. You know, have I read through all of them from front to back? Some I probably reviewed abstract, but many of these, yes, I will have read through. But, again, that's the same way that I would write a manuscript for a journal, right?

As we've discussed, there's 24 hours in a day, and I have a lot going on, so am I aware of what's here, and is here important for the reference? Yes, it is, but I don't -- so, yes,

Page 44

I'm aware of the information here, and I have read through the information. Some would be skimmed more quickly, and some would be delved into in depth.

Q. You mentioned earlier that you provided some medical literature to Ethicon for them to add to this list.

Do you recall that?

A. Yeah. I remember saying that, yes, sir.

Q. When would you have done that, and which of these pieces of medical literature would fall under that category?

A. That I -- I did not keep an itemized list, as we discussed with my billing, but as far as the generation of the drafting of the report goes, when I would generate -- when I would submit the reports to Ethicon, they would compile the information in a materials list.

Q. Without saying that the studies listed or the literature listed on the reliance list are not significant, okay, is it fair to say that the materials, the medical literature, provided in the binders T-3 through T-6 are more significant to your opinions than those from the medical literature on the reliance list that did not make

Page 45

it into those binders?

A. I -- I -- I don't know that I can say that. For me, what's in the binders is information that is important, but just because something wasn't cited or referenced doesn't mean that it's not important. It may not have just made the cut for -- for the report.

I don't know if that makes sense.

Q. Sure. What was the basis for the cut?

A. For me, the -- I forget the length of the reports. There's somewhere around 15 pages each. As a general -- I mean, you can't put everything in a report. So as far as what's the basis, I think I put in the information that I think is pertinent to the discussion, so -- but I -- does that make sense?

Q. It does. And it may be just semantics that we're circling through here.

And again, whether it's no significance, more significant, this isn't a gotcha trap or anything like that. This is simply I'm trying to help my firm and other firms when they see you down the road prepare for that. That's why we're here today.

A. And again, just to be clear, I don't feel

Page 46

like you're trying to get me.
Q. Sure.
A. I don't feel like I'm trying to skirt something or that I'm trying to outsmart you because I don't think I can. I am not a lawyer. I'm just trying to answer the question as you asked, but I think it is important for other lawyers and people asking me things to understand the knowledge that I have can -- is not all completely referenced here.
Does that make sense?
Q. Sure. And that's a different thing. You're saying that the knowledge that you have in forming the basis of your opinions is not just in the reliance list; it's your education and your experience and your experience with patients and other things?
A. That is what I'm saying.
Q. Sure. And I understand that. I understand that, and I'm not trying to marry -- first of all, you're definitely smarter than I am.
A. I don't think so.
Q. Second, I'm not trying to marry you to your opinion being solely from coming from the documents or items listed in the reliance list as

Page 47

T-2, okay? That's not what I'm doing. I am simply trying to establish what needs to be reviewed down the road when these cases go to trial.
What I don't want to have happen, for example, is there would be some study buried in here that's not in there anywhere that we don't talk about today when I'm asking you what's significant, and at trial, that be the -- what's held up, and we've not reviewed it, or other lawyers have not reviewed it thoroughly. That's it. That's all I'm doing, okay?
A. Okay.
MR. KOOPMANN: Just wait for a question.
BY MR. BRADFORD:
Q. So -- and with that foundation, I don't know how to ask it other than I've asked it in terms of what's more significant. I've asked it in terms of what's more important.
Are there studies within this reliance list of medical literature that reach a level of importance to you to support your opinions if these cases are tried?
MR. KOOPMANN: Objection. You can go ahead.

Page 48

A. Sorry. So I'm not sure that I understand what you're asking. You're asking if there are -- if there's material here that would be important to me that's not in the -- I'm sorry. I don't -- I really didn't --
BY MR. BRADFORD:
Q. Sure.
A. I don't understand the difference between what you're asking and what I'm answering.
Q. Dr. Jeppson, would you agree that the studies that are most important to your opinions are contained within the citations to your report and the additional literature of your studies contained within the binders you brought today?
A. Yeah. I think -- yes, I think that would be a fair statement. I've included the stuff that would be most important to me in the reports, but that's not everything.
Q. Okay. Thank you, Doctor.
I want to move forward to the portion of the reliance list under Production Materials. It's about two-thirds, three-quarters of the way through it.
Dr. Jeppson, contained within what's categorized as Production Materials are many

Page 49

internal corporate documents, correct?
A. Yes, sir.
Q. Okay. Did you do any independent search, dive, look into those internal Ethicon documents, or were those documents that were provided to you by Ethicon?
A. These are documents that were provided to me by Ethicon. I -- again, for internal documents, really for any corporation, I would not have access to, you know. I did not --
Q. And that's my point. You're relying upon Ethicon to provide you whatever internal corporate documents they want you to have, correct?
A. For the internal documents, I would be relying upon Ethicon or Johnson & Johnson based on what they have. I do think that for this matter it's in their best interest to be transparent. If they don't provide information to me, then, at some point, it will come out, you know, in trial or whatnot.
So -- but, yes, I am assuming that they would be transparent with me in the relationship that has been established.
Q. Regarding internal Ethicon or Johnson & Johnson documents, is it correct that, if they

Page 50

don't provide that to you, you can't review it?
A. That is correct, in contrast to the medical literature which is readily available, yes, these would be internal documents.
Q. Is it also correct that Ethicon and Johnson & Johnson choose which internal documents to provide you?
A. So, you know, as I mentioned before, I do think that is true, but I also think that it is in Johnson & Johnson's or Ethicon's best interest to provide all pertinent information so that, as an expert witness, I can have access to that and have reviewed it.
Q. And I agree with you about that, but my -- the question is simpler than that. Ethicon or Johnson & Johnson choose which internal documents to provide for your review?
A. Like I said, yes, I think that is up to them.
Q. Have you personally reviewed each of the items listed under the Production Materials category of the reliance list?
A. So I think it was probably -- it might have been longer than six months ago for this stuff, but, yes, when I went into -- to agreement

Page 51

with Ethicon to be an expert witness, I was provided the information, and I reviewed it. And that would have been around, you know, this time last year. I forget when this was signed. Was it April?
So it probably would have been, you know, May-ish or somewhere around there, April or May or somewhere in there that I received the information and reviewed it.
Q. And the time for that would be contained within the billing records you provided me?
A. I don't know that I actually included that time in my billing. What I included in the billing was everything that I reviewed for the reports and put together for the reports.
So -- but, yes, I did spend time going through all of this.
Q. Have you submitted billing invoices to Ethicon other than the one provided here today attached as Exhibit T-7?
A. The invoice for today is related to the expert reports, and so that's what is billed there. I have provided some review of patients. I've been deposed on Silva, and so that -- that I have done, but not in relation to an expert report

Page 52

or --
Q. Maybe I'm not -- if you've worked on Silva, for example, or other case-specific --
A. Yes.
Q. -- what we call case-specific in our business, I'm not interested in that, okay?
A. Okay. So I have not billed for anything other than case-specific to Ethicon.
Q. Okay. So the -- your review of the items and documents listed under the Productions Material category of the reliance list -- I just want to be sure I understand -- that's not included in the billing on -- that you provided today, correct?
A. That's probably an oversight on my part. What's included there is, when they asked me to generate an expert report, from that time forward, I tracked the time spent and added to, but I did not go back through.
I think in part -- you know, part of doing anything is having the foundation or understanding to be able to do a job. So I did not go back retrospective to a prior time with this billing.
Q. Do you have any recollection of how much

Page 53

time you would have spent reviewing the documents or items listed under Production Materials?
A. I don't recall. You know, it would have been probably a half day or a day's worth to look through and read them, to skim through and to -- to get things, and then I've gone back later, but, yeah, I don't recall.
Q. When you say you've gone back later, what do you mean by that?
A. So I've gone back through and flipped through the folders to look at either particular things or to try to refresh my memory on, you know, certain things, on certain information.
Q. Would that be captured in the billing that you provided?
A. That would be captured in the billing provided. If it was done during the time that I was generating reports, it would be captured here.
Q. And then I want to move on to the portion of the reliance list regarding company witness depositions.
Would you agree there's an alphabetized list of company witness depositions that were taken?
A. Yes, I would agree.

Page 54

Q. All right. And when would you have received those deposition transcripts?
A. So that would have been back at the beginning as well along with the production materials.
Q. Okay. And did you read each of the depositions listed in the Company Depositions Witness portion of your reliance list?
A. I reviewed the depositions that I got. I reviewed all of the information that I received, but this would have been a while ago. It probably would have been around last April that I reviewed this information.
Q. All right. And that would not be contained within the billing records you provided, today, correct?
A. That is correct.
Q. And you have not billed Ethicon for that time, correct?
A. If it was pertinent to case-specific, then it would have been billed for the case-specific.
Does that make sense?
Q. It does. And I guess I'm going to need to ask -- I wanted to avoid it, but there's the

Page 55

case that you were deposed on obviously, Silva, correct?
A. Yes.
Q. How many other case-specific -- strike that.
How many other individual cases has Ethicon hired you to review?
A. I don't remember offhand. I would have to look. I would -- I would -- you know, a very rough guess, I would say probably seven or eight, and some, you know, reached settlement before moving to deposition, and others are still ongoing.
Q. Sitting here today, do you have any independent thought or memory as to which of these depositions listed under Company Witness Depositions, if any, would have been relevant to and billed for any of the individual cases you reviewed for Ethicon?
A. That I don't remember, but, again, you know, in reviewing the production list and the deposition list, I view that as necessary to be an expert witness, and if I'm hired by someone to do a job, I need to do my due diligence so that I understand what I'm doing.

Page 56

Does that make sense?
Q. Sure.
A. So that wouldn't necessarily -- you know, like I -- just my personality, I wouldn't necessarily track all of that. It's like me doing my -- investing in my knowledge and ability.
Does that make sense?
Q. Yes, it does.
How much time did you spend reviewing the depositions provided to you listed under the Company Witness Deposition portion of your reliance list?
A. That, I don't remember. Ballpark, I'm sure I spent several hours going through it, but I -- you know, was it two hours or four hours? I don't know. It wouldn't have been more than a half day I don't think. I tend to try to be very efficient with things, so my guess would be a couple of hours.
Q. And these deposition transcripts, Ethicon chose which ones to provide you, correct?
A. As we discussed with the production materials, yes, the -- I did not do an independent law search, so they were provided, yes.
Q. All right. And to save us a little time,

Page 57

are the same answers you gave regarding the production materials for internal documents, are those the same answers regarding these deposition transcripts?
A. They would -- they would be very similar, yes.
MR. KOOPMANN: I'm going to object to that last question as vague, but it's fine.
MR. BRADFORD: Yeah. Let me ask --- I'll go through the questions then.
BY MR. BRADFORD:
Q. Dr. Jeppson, Ethicon chose which company witness deposition transcripts to provide to you, correct?
A. They provided the depositions to me, yes.
Q. And they chose which ones to provide to you, correct?
A. That is correct, they did.
Q. All right. Moving beyond the deposition portion of your reliance list, we -- there's an Other Materials section that the first page looks to be a lot of industry organization -- strike that. That's not accurate.
I don't want to ask you about all these things. I'm trying to find a general way to go

Page 58

through this, okay?
So the next page -- or, the first page of Other Materials, that looks to be industry or medical organization presentations or position statements and things like that, correct?
A. Yeah. And I don't know if there's any industry unless you include the FDA as industry.
Q. That's what I did.
A. But, yeah, essentially these are going to be position statements from medical societies, medical organizations, and then the FDA is basically what's here. There is some industry as well, yeah, you're right, Boston Scientific.
Q. Okay. So did Ethicon provide you digital, hard, electronic copies of all of the items listed on the first two and a half pages of Other Materials?
A. So this is -- this is where I get confused, and I don't mean to be hard. But, yes, they did provide them to me, but many of these I would be aware of, and I would have included to give them which they then compiled and gave back.
Does that make sense?
Q. Sure. Some of this is publically available?

Page 59

A. Yes. Much of this -- I mean, the vast majority of this is publically available. All the FDA, all the society position statements, all of this is -- you know, ABOG, all this is going to be, and it will either be publically available or available through membership to the organizations, and I belong to most of these.
Q. Sure. All right. I want to move -- I want to look to -- on Other Materials, there's a break, and I've got some notes on here. You're welcome to see them. I don't care.
But under Other Materials, it is the third to last page, okay? There's some CFR sections and then Batiste, B-A-T-I-S-T-E, trial opening presentation and some other things.
And, again, are these materials that Ethicon provided to you, or did you ask for any of this from them?
A. This list under Other Materials, much of this was provided by Ethicon. Again, this is pertinent to, I think, understanding the devices and potentially, you know, risks associated or, you know, what was provided to providers, you know, like a lot these -- or, some of these anyways would be things included in the device,

Page 60

you know, the device labeling and those types of things --
Q. Sure.
A. -- but the majority of these, yes, were provided by Ethicon.
Q. Okay. Specifically I want to ask you about, do you know what the Batiste trial is?
A. I don't recall the Batiste trial offhand, no.
Q. That's something Ethicon chose to provide you, correct?
A. That is correct.
Q. You didn't ask for that; did you?
A. I did not.
Q. Do you know why they wanted you to see that?
A. I don't recall. I'd have to go back and refresh my memory what the Batiste trial is. Then I can answer that question.
Q. I want to ask about the excerpts from the deposition of Kimberly Kenton, M.D. Do you know why Ethicon thought you should see that?
A. I don't. I know Dr. Kenton, but I don't know why those excerpts in particular.
Q. And is the same true for the Heniford DBD

Page 61

transcription?
A. Yes.
Q. Do you recall sitting here today what that is?
A. I'd have to refresh my memory.
Q. And do you recall sitting here today what the Pence, P-E-N-C-E, direct slides are?
A. And then, again, my same statement. I would need to go back and review to refresh my memory.
Q. Is the same true for Perry, P-E-R-R-Y, versus Ethicon closing statement?
A. Yes.
Q. All right. And there's an additional list of deposition testimony provided here as well, correct?
A. Yes.
Q. And I will represent to you -- well, actually that's not true. I can't say that, but there are some company witnesses in there.
Under the deposition testimony listed on the last -- the second to last page and the last page, those are depositions or portions of deposition testimony Ethicon chose to provide you?
A. Yes.

Page 62

Q. And you reviewed those?
A. I did.
Q. And just so we're clear, this isn't something you asked for Ethicon to give you; they chose to give that to you, correct?
A. That is correct.
Q. And I'm sorry. I misspoke. Just so the record's clear, I said "the second to last page and the last page," and I was wrong. The last page is actually some expert reports from MDL wave cases.
Do you see that?
A. Yes.
Q. And did you review those expert reports?
A. I did.
Q. Do you recall how much time you would have taken reviewing those expert reports?
A. I don't recall. Many of these are reports that would have been included with the case-specific. You know, each case would have an expert witness. So I would have reviewed, you know, just looking at the many -- many of them I've seen a couple of times with those case-specific, but I did read through them.
MR. BRADFORD: We've been going a little

Page 63

over an hour. Let's take a couple of minutes.
THE WITNESS: Yeah, sure. Thank you.
MR. KOOPMANN: That's what I was just going to suggest.
(Whereupon, a brief recess is taken.)
BY MR. BRADFORD:
Q. Dr. Jeppson, when Ethicon approached you about becoming an expert in this case, what about that was interesting to you?
A. From my perspective, my concern is that mesh not be an option for patients, and based on the medical literature for midurethral sling and sacrocolpopexy, mesh should be an option. And so I am concerned particularly with the class action lawsuits that were filed in Washington and other states that, if these very good options are taken away from women, we will set ourselves back, you know, 20, 30 years in what we can offer patients.
And so, from my perspective, you know, essentially the opinions in that that I have provided are in line with all of the national and international organizations, and so I want to report that there are benefits of these options for patients. That's what's appealing to me.
Q. I'm sure you're aware -- I would like to

Page 64

say three weeks ago, but it was probably six weeks ago now -- that the synthetic mesh vaginal POP kits are no longer allowed to be used; you're aware of that?
A. That was mid April, yes.
Q. Time goes.
A. Yes.
Q. Have you heard amongst your colleagues any discussion about a similar fate for synthetic meshes for stress urinary incontinence implanted vaginally?
A. There have been discussions about that for quite a while actually, but since the report came out on -- and it's the banning of the sale of pre-made kits to be used transvaginally. But after that came out, AUGS put out two -- they're not position statements, but the president of AUGS put out two statements regarding mesh. AAGL did as well. That's two As and a G and an L. AAGL did as well.
And the second issue from AUGS was specific to discussions that were had by AUGS leadership and the FDA. And one of the points in that communication was specific to the concern that many providers have in the United States that

Page 65

midurethral slings will be taken from the market.
That is not what the FDA said, but there is concern that that could be a -- you know, an indicator of things to come. And the medical community, I would say, is -- the vast majority of the medical community would not agree with that based on the evidence and what has been published regarding slings in particular.
Q. Do you have any understanding as to the prevalence of midurethral synthetic sling use over time?
A. Well, it has increased over time. It was -- I mean, it was first reported in the '90s, right, and so prior to that, it wasn't available. And now, I mean, the position statements are that it's the standard of care for most women.
Q. Do you have any -- strike that.
TVT came on the market in 1998?
A. Yeah. It was around '97, '98, somewhere around there.
Q. And TVT-O came on the market in 2004?
A. So, yeah. So the Monarc, I think, was 2001 or so, but, yeah, so around that, the late '90s, early 2000s.
Q. Sure. The first midurethral slings were

Page 66

the retropubic slings that came on the market, right?
A. Yes.
Q. And then after that came different companies' versions of transobturator slings?
A. And other slings in general, yes.
Q. Right. And then after that came the mini slings?
A. And then mini slings came later, yes.
Q. Okay. From 1998 to 2019, do you have any understanding as to the prevalence of synthetic midurethral sling usage in the country?
A. Do I have, like, a number treated per year?
Q. Sure.
A. I don't recall that offhand. I'd have to look.
Q. Or any understanding of any trending or trendline in the use of midurethral slings for stress urinary incontinence.
A. So midurethral slings would have started out being done by a few, kind of the trailblazers and then early adopters, and then it would have increased. I will tell you from experience, based on in part the FDA issuance of mesh in general,

Page 67

but then all of the advertisements and everything that go along with that, I often see patients who tell me they don't want mesh even though they really don't know what it is or what that means.
So I would suspect that, if you were to look at a trend, you would see a pretty sharp increase in mesh with the 2008 FDA, and then the 2011 and the 2016, I suspect there's probably been a little bit of a plateau or perhaps a decrease would be my guess, but I would have to look at that data.
Q. Thank you, Doctor.
I have the benefit of being provided your CV. I've got a copy. Do you have a copy of it? You probably don't need it, but I've got a copy of it.
MR. KOOPMANN: It's in one of his binders.
MR. BRADFORD: I've got a copy handy.
A. You can ask me.
BY MR. BRADFORD:
Q. You probably know it, but there you go, just in case.
I want to go through your background a little bit, not in much detail, more focused on

Page 68

your medical training and your training through residency and others that led you to be a urogynecologist as you are today, okay?
A. Okay.
Q. When did you start medical school?
A. 2002.
Q. All right. When did you graduate medical school?
A. 2006.
Q. And what specialty did you decide to enter into?
A. Do you want, like, my whole backstory, or you just want a quick --
Q. Give me the cliff notes.
A. So in medical school, I went through many different options trying to decide what I wanted to. At the end of medical school, I was thinking about either becoming a urologist or becoming an OB/GYN. The OB/GYN route was more appealing to me because at the time I was considering reproductive endocrinology and fertility or urogyn, and OB/GYN kept both options open. When I got into residency, I actually chose to do urogynecology.
Q. All right. And you did your residency at Cleveland Clinic?

Page 69

A. I did Case Western Reserve MetroHealth and Cleveland Clinic. It was a combined program.
Q. All right. And then you did an additional fellowship?
A. Correct. I did three years at Brown University. The hospital affiliated is Women's & Infants, and I was there from 2010 to 2013.
Q. All right. I want to ask you about your experience in treating stress urinary incontinence and do that by time frame.
Okay. So when in the course of your medical school or residency or fellowship did you have the occasion to first encounter patients who were suffering from stress urinary incontinence?
A. So it would have been as a third-year medical school student in St. Louis. I feel that I was fortunate to have had the opportunity to rotate with urogynecologists as a student. That would have been -- I don't remember exactly when that clerkship was. It would have been around 2004, maybe late 2004, early 2005. It would have been 2004.
And then I did a sub-I on urogynecology, and that would have been in early 2005. And that's just additional -- an elective where you

Page 70

spent more time with a particular field to get a better idea of what it is and to decide if you might want to do that.

Q. All right. And what -- actually, I don't -- during that time frame before your residency, what treatment options were you taught or told about regarding stress urinary incontinence?

A. So as a medical student, I would have learned about the options available at the time, the midurethral sling, the Burch procedure, the MMK, which predated the Burch, but is very similar, and then pubovaginal slings.

At the time -- I'm trying to remember -- I'm pretty sure they were doing periurethral bulking as well and then all the nonsurgical options, right, like pessaries. I know that I saw pessaries as a medical student. I know they talked about Kegels in didactics and lectures.

So I don't know if you want me to focus specific on surgery, but, you know, we covered -- you know, as a medical student on the clerkship, I would have had learning objectives that would have incorporated those, and then certainly on my sub-I I did.

Page 71

Q. Right. And I am interested in both the surgical and nonsurgical options, so I appreciate you going through that.

Any other nonsurgical options?

A. So are you asking at the time of being a student or just in general now?

Q. At the time of being a student first.

A. That is a long time ago.

Q. All right. Let me skip ahead. It doesn't matter.

A. Because a lot of that gets contaminated because I just published a systematic review on the nonsurgical treatment of urinary incontinence, both stress/urgent mixed, so...

Q. All right. Let's skip ahead to your residency. Did you treat patients with stress urinary incontinence during your residency?

A. Yes, sir.

Q. All right. And what did you use? What did you do?

A. So at the time, again, the -- there would have been the nonsurgical treatments that we just discussed, Kegels, behavioral modifications, physical therapy, pessary.

In addition to the nonsurgical options,

Page 72

surgeries, at the time as a resident, I saw many midurethral slings, both retropubic and transobturator. I also saw pubovaginal slings or the -- some people call them fascial slings. And they were also doing some Virtues -- I'm trying to think -- and periurethral bulking. I saw those as well. They were using Coaptite at the time.

Q. Early on during your residency, did you favor any specific -- as to the surgical techniques, did you favor any one over the other?

A. You know, at the time, I -- mini urethral slings were the most common at the time, and again, being at the institutions I was, there were ongoing NIH funded studies looking specifically at midurethral slings and other treatment options.

But my opinions -- you know, it's hard to go back and reflect on things in a vacuum because, you know, this would have been in, you know, 2000 -- the first time I would have seen a sling in residency probably would have been 2006 or '7, but there's just been so much experience since then. It's hard to disassociate the two.

But midurethral sling has kind of always been the gold standard treatment everywhere I've been unless there were, you know, indications not

Page 73

to or if the patient doesn't want it.

Q. When did you first hear midurethral slings referred to as the gold standard?

A. It would have been -- I don't think they would have talked about that in St. Louis, although they may have. I don't remember. Certainly in residency it was a discussion. That's why most people got midurethral slings. If Burch or pubovaginal slings had been the best option at the time, it would have followed the evidence.

Q. Are you familiar with the first piece of medical literature that referred to midurethral slings as the gold standard?

A. I don't know. I -- I don't remember which one was the first one, so I don't know if I do or don't.

Do you remember? Are you asking about one in particular?

Q. I'm sad to report that I do.

A. Yeah.

Q. Do you know who authored that study? Strike that. That was a bad question.

Do you know who authored that piece of literature?

Page 74

A. The first one that referred to it as a gold standard?
Q. Yes, sir.
A. I don't.
Q. And do you know what basis or citation was given for midurethral slings to be referred to as the gold standard in that first piece of literature referencing it as the gold standard?
A. I'd have to go back and look. I don't know which was the first. I know there have been many, many since then, including systematic reviews that corroborate the findings.
So from forming medical opinions, I suppose it's not that important to me to know who first coined the phrase "gold standard," but the fact that it's supported by all other medical literature that I've looked at, you know, is what I guess I base my opinion on.
Q. When did you first start implanting midurethral slings?
A. So performing them would have been as a resident, so probably 2007, 2008.
Q. Do you recall which specific manufacturers and which device you would have implanted?

Page 75

A. So at the time, AMS was still using the Monarc. We -- and Monarc was -- they were all involved in studies at the time, but certainly I used Monarc. We used Ethicon's TVT, the original TVT. They were also using the TVT-O. And I think that was it.
Q. All right. Since that time, have you implanted other different midurethral slings?
A. Yes.
Q. Tell me -- just list the ones that you've used, and as best you can, when you've used them.
A. So that was residency. In fellowship, we did some Monarcs, but they were doing more TVT-Os or TVT-O Abbrevos. And this is 2010 to 2013. We were also using the kind of standard TVT.
Q. Any others?
A. At the time, that was what we were using.
Q. What about since then, moving from your fellowship into your private practice?
A. So since that time -- I operate at two different hospitals. One of the hospitals still uses the Ethicon TVT. It also has the Boston Scientific Advantage Fit.
The other hospital where I work more commonly -- or, where I operate more frequently I should say is they had the Boston Scientific Advantage Fit. Recently the hospital changed from Advantage Fit to the Desara Blue, both regular and the TV, which is a Caldera product.

Page 76

Q. And you mentioned that's the hospital you do more of your surgeries at.
A. Uh-huh.
Q. Which hospital is that, and why do you do more surgeries at one over the other?
A. Just based on schedules. There's five urogynecologists here in New Mexico, accommodating for or time for everyone involved having different people at different places. That hospital is Sandoval Regional Medical Center. It's up in Rio Rancho, so -- I don't know -- a half hour north of UNM. And I live near there than many of my colleagues, so I see patients in the clinic and operate there.
Q. And you entered private practice in 2013?
A. So I entered -- university practice, is that what you mean?
Q. I appreciate the distinction because it is an important one. You left your fellowship and entered university practice in 2013, correct?
A. That is correct.

Page 77

Q. And you've been affiliated with the University of New Mexico since then?
A. Yes, sir.
Q. Okay. Since you left your fellowship and entered the university practice, how many midurethral slings have you implanted?
A. I don't know. It's a very common procedure. I would guesstimate hundreds, if not thousands, but I don't know that. That's a guess.
Q. And of those -- we can answer by number or percentage, whatever is easiest for you for each device. How best could you tell or explain that to me?
A. So since graduating, just based on what they have at the hospitals, you know, just -- I would say off the record, if we weren't having a conversation that's on the record, but I think TVT, the original TVT, is still my preferred just because that's, you know, what I used the most in training.
Since being here in New Mexico, what I've used the most is the Boston Scientific Advantage Fit because that's what they've had at the hospital. You know, if you were to ask me in three years, it would probably be the Desara

Page 78

because we've, you know, recently switched to that. So at some point, those numbers will catch up and then surpass.

From my perspective, it's not necessarily important the brand or the manufacturer. It's really the placement of the -- the mesh that works, so...

If, you know, somebody were to approach the hospital and provide them a better cost than the Caldera, I would go with them. I presume that they have similar data.

Q. Have you implanted a TVT-O since you left your fellowship in 2013 and went into university practice?

A. TVT-O, I have not.

Q. Have you implanted a TVT Abbrevo since you left fellowship and went into private practice?

A. I have not, but only because they don't have it at the hospital. And as far as the TOT option goes, I prefer the Abbrevo actually. I prefer the in to out.

Q. Over all other transobturator slings?

A. Again, I think that they are similar, but just for me personally, yes, I would -- I just

Page 79

like -- I like the in to out. I like the dissection doesn't have to be as big. You don't have to get your finger in to feel it coming through, and I feel it's a very good option.

Q. Do you agree the Abbrevo is a mini sling?

A. I think that the Abbrevo is a shorter sling. I would not categorize it as a mini sling. I think it's different than the mini slings.

Q. Have you ever authored an article that referred to the Abbrevo as a mini sling?

A. I've authored -- I've been a coauthor on a manuscript that looked at the TVT-O Abbrevo. I don't recall if it was mentioned as a mini sling in that manuscript. It may be. I think that it depends on how you define mini sling.

And you know, it's not the full length sling that is cut at the skin after implantation. It's shorter than that. But it's not -- you know, it doesn't have a pledget or something on the end that you're sticking into a membrane or something to hold it in place because, you know, like the Contrasure or the TVT securities are the kind of, you know, traditional, more -- I think what I would refer to more commonly as a mini sling. It's -- I think the mesh goes through the

Page 80

obturator membranes in that. I think it goes further out.

Q. How long is the TVT retropubic?

A. I don't remember. I'd have to look at the -- I'd have to look at it. And it's -- I don't know how long that is.

Q. All right.

A. It's long enough to go through the periurethral tissue, retropubically come out of the pubic -- the suprapubic incision sites and still extend beyond that, even in obese patients, but I don't know the length.

Q. All right. And do you know the length of the TVT-O device?

A. So the TVT-O, not the Abbrevo, would be a similar length, in my opinion, because it also comes all the way out through the groin incisions, but, again, I don't know the full length.

Q. Do you know the length of the TVT Abbrevo?

A. The TVT Abbrevo is shorter, and I would have to look at that as well. The number -- it's somewhere around -- 10 centimeters is the number in my brain. It might be a little bit more or a little bit less than that.

Page 81

Q. It's 12. I'll represent to you that it's 12.

Since you've left -- strike that. I need to lay a foundation.

During your fellowship, did you perform any Burch procedures?

A. Yes.

Q. How prevalent was your Burch procedure implant use during your fellowship?

A. It was not -- it was not uncommon. We probably did about as many Burches as I did pubovaginal slings. The midurethral sling was still the mainstay, but I did some pubovaginal as well as some Burches. I don't recall the number offhand.

Q. Roughly, what percentage -- strike that.

Before we get there, did you perform MMK during your fellowship?

A. So MMK is different than Burches essentially in where you place the sutures at the pubic symphysis. So there is a some data that MMK have higher risk as far as osteitis pubis because you're putting the needle into the periosteum.

The Burch, you go a little bit more laterally and put it into Cooper's ligaments. So

Page 82

could I do an MMK? I'm certain that I could, but I would choose to do a Burch over that.
Q. Have you ever done an MMK?
A. I have not. I've seen them done. I have not done them, but the technique would not be different. You're still in the same place. It's just where you place your suture.
Q. And during your fellowship, did you use bulking agents?
A. Yes.
Q. And how -- is that something that you did often?
A. I did them more frequently in fellowship than I do now.
Q. All right. I'm going to ask you by percentage if you can answer this for me, okay?
By percentage, if we look at midurethral slings -- let me strike that.
I'm going to ask you some questions about your fellowship, during your fellowship time period, the surgical treatment for stress urinary incontinence, okay?
A. Okay.
Q. Okay. And I'm going to ask about midurethral slings, Burch, pubovaginal sling, MMK

Page 83

and bulking agents. If you could describe by percentage --
A. How many?
Q. -- how many.
A. So the thing with percentages is it's proportion, right, so I think, to set the foundation for this discussion, it's important to state that I trained at a high volume center. As far as urogynecology goes, I feel very fortunate to have trained at premier institutions, Cleveland Clinic and then Brown. At the time, most people considered those to be one and/or two as far as the best training facilities for what I do in the country.
Number of cases per year, I don't remember, but I did have to keep a case log as part of being a trainee. We did a lot of slings. I probably -- I probably -- you know, out of everything, it was probably maybe 85 percent sling would be my guess, and this is midurethral sling. And I'm not differentiating between transobturator versus retropubic. That would be hard for me to do, and it would probably be a 50/50 breakdown there, but I would have to think about that.
As far as the next most common option,

Page 84

probably periurethral bulking would be my guess. Probably somewhere around 5 percent. I know my numbers aren't going to add up. And then Burches and pubovaginal slings would have been less common, and I don't -- I don't know a percentage for those. They would have been a little less common than bulking, so maybe, you know, 3 percent each or something like that, but that doesn't add up to a hundred.
Q. It's okay. It's close enough. It describes it well enough for the purpose of my question.
Now I want to ask you the same questions in your university practice since you left your fellowship.
A. So in the systematic review that was just published, we did include periurethral bulking as part of that. The periurethral bulking did not have very favorable outcomes. I don't do a whole lot of bulking. Bulking is thought to be more transient, and there are complications associated with it. So I do offer bulking, but I don't perform it very often, and that's by choice.
The -- you know, I probably still -- I don't know. Probably -- I'd say I'm probably

Page 85

still 85 percent sling would be my guess. I'm probably 10 percent Burch, and I'm probably, you know, 5 percent pubovaginal sling or maybe a little less than that.
Q. In your personal experience in your hands, since you've been in university practice, how do they compare?
A. In general, my patients do very well. I think that there are different indications for different patients. The climate that we are in, I will often see patients who don't want mesh.
And -- you're from Florida?
Q. Yes, sir. Panhandle, Pensacola.
A. So New Mexico, just patient-wise, is kind of like Vermont, New Hampshire or Oregon. It's just a little more granola kind of like. You know, naturopathic kind of stuff happens a lot here. So some is patients come in, and they simply don't want mesh, and so, for them, I offer a pubovaginal sling or a Burch.
For patients who have had mesh before and had problems with mesh or have a family member who had problems with mesh, they also don't want mesh, and I would offer them a Burch as well. But, again, you know, the predominant thing that I do

Page 86

is midurethral sling. Having used different brands, you know, again, I'm not married to a brand. It's really more the placement of the device that I think is helpful, if that makes sense.

Q. Sure. You mentioned that your patients do very with all the procedures. Strike that.

You don't like bulking agents, but as far as the midurethral sling versus Burch or pubovaginal sling, they do very well?

A. So as a general rule, yes. I mean, that is not to say I don't have complications. Everybody does, and not every patient is completely cured. I wish they were, but that's not the reality of life for medicine.

But in general, yes, patients do well.

Q. Do you agree the risk profiles are different for synthetic midurethral slings as compared to Burch or pubovaginal slings?

A. Yeah. I think that the literature supports that.

Q. And does your personal experience support that also?

A. Unfortunately there are no surgeries that do not have risks, and so it's just a matter of

Page 87

which risks you're assuming with different procedures.

Q. Have you ever done a partial or total mesh removal?

A. I have.

Q. Okay. I want to talk to you about your experience with removing synthetic meshes. When did you first do that?

A. So when I was a medical student, I saw a mesh removed. I don't remember the brand. At the time, it was a transvaginal mesh. I saw a few of those. As a resident, I saw mesh removed as well and as a fellow.

As a fellow, we did a decent amount of mesh removal mostly referred in from other providers that were fashioning their own mesh. They weren't using a particular product, and they were placing it incorrectly, and it led to problems for patients, and so we would take it out.

Q. So that would not be the midurethral slings we've been talking about today; that would be a --

A. A self --

MR. KOOPMANN: Hold on.

Page 88

BY MR. BRADFORD:

Q. Sorry. Let me finish my question. We've done so well with this. It's okay. We're doing just fine.

When you say they would fashion it themselves, what do you mean by that?

A. They would take a sheet of mesh and cut a portion, and then I don't know if they were using a staining needle, and I don't know because I didn't do it with them. They were, you know, a provider in the community, and they were -- I don't know if it was top down or bottom up, but they -- the mesh was placed in a way that caused problems for patients.

Q. Did that just happen to occur in the geography or geographical area close to where you were doing your fellowship?

A. It did for the first two years, and then that provider moved, and the complications stopped.

Q. Okay. During your fellowship, did you have the occasion to remove totally or partially midurethral slings from one of the sling kits?

A. Yes.

Q. Okay. And how often did you do that?

Page 89

A. As a referral center, you know, we would get cases from all over the region. How often did I do them? I don't know. It was not -- I did it enough that I was very comfortable with it, but I don't know a percentage.

Q. Not speaking to the one particular doctor who apparently there was a problem with, more the traditional mesh kits, do you have an estimate as to many total or partial revisions you would have done as a fellow?

MR. KOOPMANN: Objection to form.

A. I don't recall. It was -- again, it was -- it was -- it was not -- I don't know the number. I don't actually remember. It was not -- I would -- how many would I have done in all of my training?

And we're just talking midurethral sling, or we're talking any mesh type?

BY MR. BRADFORD:

Q. Well, that's actually a good point. Let's broaden it out to the POP kits also.

A. So any, probably, as a fellow, I would probably do one a month would be my guess. So in three years, probably somewhere in the range of 40, something like that.

Page 90

Q. Sure. And that's my next question. I was going to see if we could talk briefly about that, if there would be a way to do it.

Same question for your time in university practice. Do you do total or partial synthetic mesh removal?

A. It depends on the patient and what type of mesh they have and what's going on with the patient.

At the university practice, we are the referral center for the region, so we get patients from New Mexico, parts of Arizona, parts of Texas, you know, surrounding states. You know, patients will often travel four or five hours one way to come in.

Because of that, I think that there may be -- well, I know there are people that are doing things perhaps they don't do very often or perhaps shouldn't do, and so I do get referrals from mesh issues and mesh complications, both of the transvaginal mesh as well as the sacrocolpopexy mesh as well as the midurethral sling mesh.

Going in to take those out, it often seems apparent to me that the mesh was not placed correctly. If I remove mesh and it's in front of

Page 91

the pubic ramus, that's not where it's supposed to be, so it does not surprise me that the patient would be having pain or issues.

From within my own practice, it is a rare occurrence to have problems with the slings. That is not to say that I always place them correctly or that my partners do. On occasion, I've had to go back and release a sling.

You asked about removing mesh in its entirety versus partially. I think it depends on what's going on with the patient. For patients that are having pain issues from mesh, I tend to try to remove as much as I possibly can. For patients that are having obstructive voiding issues or other things like that, there is data to suggest that potentially only taking out a small portion and not all of it may actually lead to better continence down the line.

That said, I discuss the options with the patient, and I give them the option of me removing as much mesh as possible versus taking out a portion of. I don't know if you want me to expound on how I do that or --

Q. Sure. Well, before you do, monthly, how many partial or total mesh removal surgeries do

Page 92

you do on average monthly?

A. I would say I probably average one a month. And the midurethral sling removals, those kind of blend together because they're fairly straightforward and simple.

If I'm taking out mesh because someone dissected and placed it in the bladder, those tend to be much more memorable. Or if they dissected through and the whole mesh is coming through the vagina, those are also memorable. But I would say, on average, about once a month.

For the midurethral sling removal, I would start with a vaginal incision and would take the mesh out vaginally. If it was a transobturator sling, the Savada who practiced and practices at the Cleveland Clinic published, you know, back in like 2001 or '3, somewhere back there, that you can often just take the mesh and roll it around a clamp, and you can bring it back through the obturator space. I have done that successfully.

Retropubically, if patients want all the mesh out and allow for a laparoscopic procedure similar to laparoscopic Burches that I do, you can make an incision through the perineum, which are

Page 93

laparoscopic, release the bladder down from the retropubic space, and you can take the mesh out from the retropubic space.

Q. Dr. Jeppson, do you also in your university practice treat stress urinary incontinence -- patients with stress urinary incontinence nonsurgically?

A. Of course.

Q. And what -- since you've been in the university practice, what nonsurgical options do you offer?

A. So I offer patients everything for -- anything that's been published that has data I would offer patients, so Kegel exercise. There's over-the-counter Impressa which is made by Poise. It's like a tampon made specifically for stress incontinence. There's different pessaries that can be used. Pelvic floor physical therapy, we have therapists that work with us. Those are the things that come to mind.

Q. How do your patients generally do with the nonsurgical stress urinary incontinence treatments?

A. I would say that my experience is similar to the published data. It depends on the severity

Page 94

of symptoms and what's going on with the patient. It also depends on the timing of the complaint.

If a patient has just had a baby and they have stress incontinence, it's probably going to improve over the course of the next six months to a year. There's data that physical therapy would help that, but, you know, those will get better.

In general, stress incontinence will get worse with age, and so, you know, a lot of patients, as I've discussed, prefer holistic or nonsurgical options, and so they will come in -- and I can't say that all, but I'd say the majority of patients would prefer a nonsurgical treatment to start, so I offer those, and they try that.

When those fail or if they aren't as successful as the patient would like, then they come back, and we discuss additional options.

Q. What percentage of your patients if offered nonsurgical options end up satisfied enough to not make it forward to have surgery?

A. That's a good question. I would -- I would -- I think my gestalt is probably 60 percent of patients that come in elect for a nonsurgical to start. Probably 40 percent or so would go straight for surgery, but many of those will have

Page 95

already tried nonsurgical options by their referring providers.

Of those that choose nonsurgical options, I don't know. Again, it depends on the patient and, you know, what their goals are, and if they're, you know, trying to get back to running marathons or back to cross-fit, they're much more motivated than if they, you know, want to be able to jump on the trampoline, you know, once a year with their grand kid. So I don't know. Maybe 20 percent, 40 percent would perhaps not move on. That be would my guess over the course of their life.

Q. Has your informed consent for midurethral slings changed over time from when you first started doing them as a fellow to now?

A. That -- I don't think so. The FDA notices came out in 2008 and 2011, both of which I was in training for. You know, I discuss options with patients. You know, they include non-mesh as well as mesh. I don't think it's changed a whole lot.

The conversation has perhaps become more involved as patients have become more aware. I think that has probably occurred, but I think the

Page 96

risks that I would discuss with patients, I think, you know, is more or less unchanged.

Q. As part of your informed consent for patients who are considering midurethral slings, do you discuss with them the mesh-related risks of the procedure?

A. I do tell them that it is a mesh procedure, and I do tell them there are risks associated with mesh.

Q. And what risks do you tell your patients are associated with mesh when you're doing an informed content for a midurethral sling?

A. So in general, the risks associated with mesh -- I mean, there are risks with any surgery, right? So typically, when I'm counseling, I'm offering them mesh versus non-mesh, and so often I will lump the initial counseling because there's risk of bleeding. There's risk of infection, you know, all those things that are common to surgery in general. Those would go along with the pubovaginal sling and the Burch as well and recurrent UTIs, voiding dysfunction. I mean, those are kind of across the board.

Specific to mesh, there are risks of mesh, risks of, you know, obstructive voiding

Page 97

patterns. There's risks of the procedure not working. They could still leak. There's risks of developing pain or dyspareunia, you know, pain with intercourse. There are risks of mesh exposure or erosion. There are risks of mesh getting into structures that it shouldn't be in, the vagina or the bladder, and then very rare risks, you know. But, you know, ureteral injuries have been reported. You know, large vessel injuries have been reported. Those are very uncommon.

Q. You've not experienced any of those with your patients, I wouldn't expect, the ureteral or a major blood vessel injury?

A. I have not.

Q. I just want to be clear. You mentioned pain and dyspareunia. Are those separate mesh-related risks that you mention to your patients?

A. They can be separate. Some patients only have pain with intercourse, and if they have an erosion or exposure, sometimes their partner will report, you know, discomfort during intercourse, but some patients will just have pain at baseline.

But, again, that's true after any

Page 98

surgery, and that occurs after, you know, vaginal prolapse or vaginal hysterectomy cases as well.
Q. Certainly there can be pain from any surgery, but would you agree that there can be pain associated with mesh implantation?
A. I would agree with that, just like with any surgery.
Q. Well, I'm asking a little different question. I'm not talking about a general surgery risk of pain. I'm talking about a risk specific to mesh.
A. There is a risk specific to mesh, and that's in the published literature as well. Again, just like with other procedures, there is surgery-specific risks.
Q. This is an important issue, so I want to be sure we're not going in a circle here.
There's a surgery -- general surgery risk of pain with surgeries, correct?
A. Uh-huh.
Q. And with mesh itself, in addition to the general surgery risk of pain, there's also the risk of mesh-related pain; isn't there?
MR. KOOPMANN: Objection. Go ahead.
A. So I mean, there is, right. Any time you

Page 99

implant -- any time you use an implant, there is a risk of pain, and that's true for, you know, any implant. You know, again, I think that -- what I would say is, you know, Burches and pubovaginal slings also carry risks, right, so when I'm counseling the patient or discussing these risks with a patient, it's not like, you know, you can have mesh which has pain, or you can have this other surgery that has no risks with pain.
There are risks associated with any surgery. So if you're asking, is there a risk specific to surgery, the answer is yes, we've discussed. Is there a risk associated with mesh in particular? Yes, there is a risk of that.
BY MR. BRADFORD:
Q. You would agree that the synthetic midurethral slings are designed to be permanent implants?
A. I would agree with that, yes.
Q. And would you agree that patients who are implanted with midurethral slings such as the TVT, TVT-O or Abbrevo carry a lifelong risk of dyspareunia?
A. I think that women in general have a risk of dyspareunia just by gender unfortunately. I

Page 100

think that, if you look at the published literature, most issues of complications related to mesh occur within -- most of them will occur within a short time frame after surgery.
Certainly there is a risk. As long as there's an implant, there could be issues with that, and again, that is not specific to mesh. That is true for any implant.
But, yes, the device is meant to be implanted, and it's meant to be a permanent implant. So as long as the implant is there, there could be issues with it.
Q. You would agree, with the Burch procedure, there is no permanently implanted device?
A. So I would not agree with that. What I would say, with the Burch procedure, people place permanent sutures. I personally use Prolene. Other people I know use Gor-TEX and things like that. It's the -- the amount of material is less, and how it's placed and where it's placed is different, but if you were to place a dissolvable or absorbable suture, you're not performing a Burch or an MMK.
And I was in a national meeting maybe

Page 101

four years ago, and one of the presenters got up and presented about a Burch. And a woman from England got up and kind of chastised him for not doing, you know, two sutures on either side. They were permanent. They were meant to stay in place. So I don't know that I would agree that there's not something permanent placed.
Q. But it would be a sutures as opposed to a piece of woven synthetic mesh?
MR. KOOPMANN: Objection.
A. It is a suture instead of a mesh, and that is inherently different between the procedures.
BY MR. BRADFORD:
Q. Would you agree that the complications potentially associated with the failure of a mesh device necessitating removal are potentially greater than when a suture has to be removed in a non-mesh surgery such as Burch or a pubovaginal sling?
A. I don't know that I would agree with that. I think the risks are internally different. I wouldn't say that they are necessarily greater. Burches have a higher risk of bowel injury if you're doing them laparoscopically. If you're

Page 102

doing them open, then patients tend to have more pain, and there are other risks separating the muscle from the pubic bone. You know, things that -- they have a higher risk of infection.

So I don't know that -- and I've also -- I've also seen sutures in the bladder from MMKs and Burches where the knot is placed too low, and over time it's eroded into the bladder, and the patient comes in with voiding dysfunction issues. You go in and find they have a stone stuck to a stitch that's in the bladder that needs to be removed. So the risk profiles are different.

Q. Would you agree that it's easier to remove a suture than a woven synthetic mesh?

MR. KOOPMANN: Objection.

A. I think that any time you discuss surgery, the ability to perform a surgery is based on training and ability and experience. I would not say the removing of a midurethral sling is a terribly difficult or challenging case. I think that going into the retropubic space to take out a stitch would probably take me longer than to take out a midurethral sling.

And certainly, if all you're doing is going in and releasing a portion of the sling,

Page 103

that would be a very quick surgery. And again, you'd avoid the abdominal cavity. And that's not to say that I don't think that Burches or pubovaginal slings should be done. You know, I think they should, but, again, there is no procedure in medicine that is risk-free. There just isn't. I wish there were.

BY MR. BRADFORD:

Q. You would agree that certain procedures carry more risks than others?

A. I would agree that certain procedures carry different risks than others, right. And so, if you were to look at one risk, you know, this versus that, well, yes, one will have more. But if you're looking at this or this or this or this or this versus that or that or that or that, you have to take into account the combination of potential risks.

And you know, I would -- would I want voiding dysfunction as opposed to a bowel injury? Like, I don't know. I don't really want either, right, but different procedures have different associated risks.

Q. Do you agree that the frequency of the risks is an important factor?

Page 104

A. I would agree that that is an important factor, yes.

Q. Would you agree that the treatability of certain risks should it occur is an important factor?

A. I think the ability to treat an issue, yes, is important.

Q. Do you agree that the severity of the potential risk should it occur is an important factor?

A. Yes, I would agree with that.

Q. And would you agree that the potential permanency of a risk should it occur is an important factor?

A. I mean, you know, I think that all of these things -- yes, I mean, I would agree. You know, you have to take all of these different things into account, but the thing that I think is important to realize is that these are often conflicting issues, right?

Like, sometimes the permanency versus the severity are not necessarily the same thing. And you know, I fortunately never had a patient who's gotten a bowel injury and ended up with an ostomy, at least not since I was a trainee. It's a

Page 105

terrible outcome. I hope I never have that, right? And so, you know, again, I think, as a surgeon, as a physician, there are certain risks that I assume and that I help patients understand there are risks of when making decisions, but those are things that are taken into consideration, yes.

Q. Do you agree that if a company such as Ethicon has knowledge of the frequency of a risk that it had should relay that information to doctors to whom it is selling --

MR. KOOPMANN: Objection.

BY MR. BRADFORD:

Q. -- the device?

A. I don't think so personally. You know, again, as we discussed when we were going through the materials form or whatever the form is called, right, there's information that is necessary for a company to operate.

As a physician, what I base my opinions on and the information that I use is based on what's in published literature primarily. So, you know, I think that ethically, you know, if a company is trying to sell something that's harmful or not good, I think that's ethically wrong, but I

Page 106

don't know that it's up to the -- the company to contact every physician and tell them every possible thing that could go wrong.

Based on how medicine is practiced in the United States, at least based on my understanding, there is the learned intermediary, which is that, as physicians, we have the obligation to learn and understand what we're using to treat patients. And so I think that part of my training, that the onus is on me to learn and know what I'm doing.

Q. You work in a university setting, correct?

A. That is correct.

Q. You're certainly aware there are other physicians who implant midurethral slings that do not work in university settings?

A. Certainly.

Q. And there are people who don't have clinic a couple of days a week, that they have a clinic or in the operating room every day a week because they have a patient-driven practice as opposed to a university setting, correct?

A. Certainly, yes.

Q. And you would agree that you have more time based upon the nature of you being a

Page 107

professor, and the nature of your practice to review literature as opposed to these in the trenches doctors?

MR. KOOPMANN: Objection.

A. I would disagree with that. I would think I have 24 hours a day just like anyone else. I think that, if I chose to go into private practice and I chose to see patients five days a week for ten hours a day or 12 hours a day, that would be my choice.

My obligation to my patients is still to provide them excellent care. So, you know, how I choose to divide up my day is up to me to a certain extent, but, again, I don't think that the -- I don't think that it's up to Ethicon or Boston Scientific or, you know, any of the drug like companies. I think it's up to physicians to know what we do. That is why I went to medical school, and that's why I have a medical license, and that's why I do my maintenance and certification every year to keep up on these things.

And then, being in academic practice, there are benefits to keeping up on the literature, sure. Students ask me stuff.

Page 108

Residents ask me things. Fellows ask me things. And it kind of makes you think.

BY MR. BRADFORD:

Q. Do you think companies have an obligation to advise physicians to whom it is selling its devices about the risks of the device?

A. I think that companies should be compliant with whatever the federal mandates are. And if there are -- you know, the FDA is in place for a reason, and if -- if government agencies have things in place, I think that companies should be compliant with said regulations.

That said, when we have representatives from different companies come out and talk to us, which they do, I always take that with a grain of salt because I want to get my information from the medical literature based on the studies. You know, I don't -- so, again, I guess I don't think that it's up to the company to provide me all the information. I think that's up to me.

Q. So just so we're clear, it's your opinion that medical device companies do not have an obligation to provide the risks of its products to the doctors to whom it is selling them?

A. I think that medical device companies

Page 109

have an obligation to be compliant with the mandates set forth by the government in the country in which they operate. In the United States, I think that, you know, if the U.S. Government were to set up a mandate or a requirement that companies inform and educate providers, then they should be compliant with that.

If that is not the expectation of the regulators, then I think that the companies should be compliant with what they think is right, and of course, being ethical, but, again, I don't go to a company and say, I'm going to use your drug. Provide me all the information on it. I go to the lexicon, or I go to another source to find my information. I am not relying upon them telling me. That's why I went to medical school. That's why I went to residency. That's why I did fellowship.

Q. Dr. Jeppson, you mentioned ethics a couple of times in this deposition. Do you think it is ethical for a company to not disclose risks to physicians of a product or medical device that it knows about?

MR. KOOPMANN: Objection.

Page 110

A. So -- so, again, you know, I think that -- I think that a company, you know, should -- should provide information that's -- that's pertinent, but, you know, I don't think it's possible for a company to provide all possible outcomes to a surgeon.

So, you know, things that would be reasonably associated and not commonly known, that would make sense to me, right? So you have -- you know, in medical school, as I discussed before with the Burch and pubovaginal sling, you have risks of bleeding. You have risks of infection.

Those are commonly known complications. I don't need Ethicon or anyone to tell me that those things can happen with surgery. You know, rare things like, you know, fistula and other things that happen very, very infrequently, I also know about.

I think that -- you know, again, I think that -- I think that companies should be compliant with regulations.

BY MR. BRADFORD:

Q. Do you hold yourself out to be an expert in FDA regulations?

A. So what I would say is I -- as a

Page 111

urogynecologist, as a practicing surgeon and physician, I understand the pelvis. I know -- I have a very, very sound understanding of anatomy. And so, you know, as far as devices that are placed in the pelvis, I feel like I understand where they go and what they should do if I'm going to use them.

Am I -- am a regulator? I am not. I don't work for the -- actually I do think I work for the Federal Government, for the university, but I am not a regulatory body of the FDA to -- to ensure compliance.

Q. Have you ever written an IFU for a product?

A. I have not written an IFU for a product.

Q. Have you ever designed a medical device?

A. I've had discussions with people about medical devices. That's not what I choose to do with my career.

Q. So you have not designed a medical device?

A. I have placed mesh in the pelvis. I've done freehand mesh. I've done these types of things for very similar products that are available on the market. Could I develop one? I

Page 112

think that I could actually. Have I done that? I've chosen not to.

Q. Kind of bringing us back. So if Ethicon has knowledge of the frequency of mesh-related risks, it's your opinion that it has no obligation to disclose that knowledge to doctors?

A. I think that they have an obligation to divulge that information to -- to the entities that govern them. So if you want to sell products, I think that you should demonstrate the -- they have efficacy and that they are able to be -- that they should be used.

But, again, I don't think that they have an obligation to go to every physician in the country who may or may not use their product and educate them.

Q. Well, couldn't they do that simply by putting it in the IFU?

A. So, again, in my opinion -- and this is substantiated by the medical literature -- most providers don't read the IFU. And, you know, when I was in training in Cleveland and in fellowship, actually I was told that, if you're going to use a device, you should read the IFU so that you know what's there, but I will tell you that most people

Page 113

don't.

And so, you know, again, I think that most physicians get their experience through training, hopefully. That would be the ideal. As a trainee, for things that develop after you're done with training, it's up to the physician to learn and augment their skill set. So if that means going and shadowing someone else or doing something, I think that then you need to do that.

Again, I don't think that -- I would not seek my medical knowledge from a medical corporation. I would seek my knowledge from the literature and from other providers.

Q. Could -- strike that.

You would agree that Ethicon has sales representatives; I think you mentioned that earlier, correct?

A. I believe that all companies have sales representatives.

Q. And they call on physicians such as yourself from time to time?

A. Yes.

Q. And they provide information and data to physicians such as yourself from time to time?

A. From time to time, yes.

Page 114

Q. And certainly, you would agree that Ethicon could put a card within each synthetic mesh device that lists the frequency information it knows; couldn't it?

A. So, you know, again, getting back to -- you know, I've performed systematic reviews. I've done systematic reviews looking specifically at adverse events. If you were to take a snapshot of the medical literature at any given time and then redo that six months later, you will find that there's a shift based on what has been published, right?

There are -- also, it's impossible, in my opinion, to tell a given provider or physician what their complication rates may or may not be. As we have discussed, I know that there are providers in communities where I've lived that have much higher complication rates than I do. So if I were to look at a card in an IFU and it tells me that the complication rate is 2 percent, and I look at my own patient population and I have a complication rate of 90 percent because I'm a terrible surgeon, the card is not accurate, right?

Conversely, if as a good, trained physician, if I know what I'm doing and I'm doing

Page 115

things that I know how to do and something says it has a complication rate of 10 percent, maybe my complication rate is 2 or 3 percent.

So I don't think that -- again, I do not believe the onus is on a company to provide all rates of all possible outcomes be they good or bad to physicians. I think it's up to the physician to look at the literature and know what they're doing. And if a surgeon can't do that, they probably shouldn't be doing the procedure.

Q. So instead of the company telling surgeons what it knows, the surgeon should do additional homework to figure that out even though the company already knows it; is that your testimony?

A. I don't think that's what I'm saying. What I'm saying is that it's not up to the company to compile all that information and divulge all that information. I think that a -- again, I think that there are inherent differences between what a company has an obligation to and what a provider has obligation to.

And so, again, you know, should a company, if they have a product that's causing harm, should they recall it? Yes. Should they go

Page 116

around and educate every physician in the world that they have a terrible product? Probably not.

I think they withdraw it from the market. If there's data to support they have a good product that also has some associated complications or harms, well, then it's up to the physician to weigh the risks and benefits.

And again, this is not specific to mesh litigation. This is true across the board for heart surgery or for neural implants or anything. I mean, there are no surgical procedures that do not carry risks.

(Whereupon, a brief recess is taken from 12:04 p.m. to 12:17 p.m.)

BY MR. BRADFORD:

Q. Thank you, Doctor. Back after a quick break.

There are terms that we hear a lot in this case. It's erosion, extrusion and exposure.

Do you use those interchangeably or do they have different meaning to you?

A. I think that, in general, for most practitioners, they are interchangeable. If you look at the medical literature, they do tend to have more specific meaning, but the meaning is

Page 117

defined by the particulars studies. So if you were to tell me exposure versus erosion versus extrusion, I would probably think you're talking about the same thing. In the literature, some people say exposure if it's a parent right after surgery, whereas erosion might be if it occurs at a later time, but I think most practitioners use them the same.

Q. Okay. I'm going to ask you a couple of questions and the only reason I ask that is because I'm going to ask you some questions about erosion, and I don't want to give you a hypothetical. I just want to make sure we're talking about the same thing.

So by "erosion, for these questions, I'm referencing erosions, extrusions, exposures, okay?

A. Okay.

Q. Specifically as to the risk for the Ethicon TVT, TVT-O and Abbrevo midurethral slings, if the company has knowledge about the frequency of erosions, would you agree that's something the company should share with doctors to whom it sells the products?

A. Yeah. Again, based on the way that the regulations are set up, as a physician, if I have

Page 118

a complication, I'm not reporting that to the company. I'm taking care of the patient. I'm treating things, right? So if the company is doing those independent trials and studies, those could be published.

If -- if they're doing the regulatory requirements to get through to market, then, again, those should be looked at by the regulatory agencies.

So, again, you know, I think that as a provider, what I care about more is what's happening in practice. And so if, you know, again, I can give you the Scandinavian data is a good example. If, you know, you have Sweden or a country that has universal healthcare and they track their outcomes, and they post, you know, rates based on 50,000 women, I'm going to care a whole lot more about that than if the company said, Oh, we did this study and we had 12 women per arm and this is our rate. Does that make sense?

So what I care about is what the rates are, but I expect and anticipate that I will get better information from the medical community than I would get from the manufacturer. Does that make

Page 119

sense?

Q. It does.

In this case, you've had the opportunity that almost all practitioners have not had in that you've had a chance to look into the underbelly of the corporate documents and corporate depositions, correct?

A. Yes, sir.

Q. And would you agree that puts you in a unique position to know more about what the company knows about its products and devices, specifically these slings than the average practitioner?

A. I would agree that I know more than the average practitioner, but I would say that it hasn't changed my practice. It's not like I've discovered something and was like, oh, if everyone knew this, it would be this big huge conspiracy and then everyone would change the way they practice.

I still base my practice on the medical literature. So are the company documents interesting? Yeah, I'm kind of a geek in that way. I do like to know things, but, again, does it change the practice of medicine? No, it

Page 120

doesn't.

Q. Dr. Jeppson, as an expert in this litigation, is there anything that you have seen from the company documents you think should be made known to the doctors who use the Ethicon midurethral slings?

A. You know, again, I -- I can't really think of anything. You know, in -- in looking through the documents and looking at the internal, yeah, there were some, you know, offhand comments and those kind of things and, unfortunately, those kind of things do happen.

Do I think that would be important for all practitioners to know? I don't think so. And, again, I'm basing my decisions and my treatment on high-quality data, right? Like the systematic reviews, the randomized controlled trials. And so if there's some small absurd or, you know, whatever, like, it doesn't really impact the overall efficacy or risk profile, you know, risk/benefit profile of the device.

Q. Sure. Is there anything in the corporate documents that you've seen that you think Ethicon should tell doctors who used the midurethral slings about?

Page 121

A. Not that I recall right now. I can't think of anything, no.

Q. Dr. Jeppson, is there anything that you've seen in the corporate depositions that you've reviewed that you think Ethicon should advise doctors to whom it sells its midurethral slings?

A. I can't think of anything offhand, no.

Q. You mentioned a word in the doctrine earlier and, of course, we're all -- everybody here is at least familiar with that, but I want to ask you some questions beyond that.

Do you think that the patients who are considering what to do for their stress urinary incontinence deserve to know about the risks that Ethicon knows regarding its midurethral slings?

A. I think that patients need to know information that impacts them and their ability to make a decision. Ideally, I would love if patients knew everything, right? They know everything. They come to me and they're really coming to me as a technician. That is not how medicine works.

And, you know, in having had, you know, thousands of discussions with patients regarding

Page 122

healthcare, there's a point in a conversation where their eyes will kind of glaze over and they just can't -- they can't process the information and they don't have the underlying medical knowledge to make the -- the discrimination between various amounts of information.

And oftentimes, a patient will say, Well, Doctor, what would you do? And then I would tell them, Well, I am not -- I can't be paternalistic. I'm not here to make a decision for you. You know, this is the information and you need to make a decision.

So, you know, again, I don't -- you know, I don't think that patients should be going to a company to ask the company what they should do. I think that patients should talk to their doctor and make a decision based on what their individual goals are and what they hope to achieve.

Q. I'm actually asking the opposite.

I'm asking should the company let patients know, be it through the patient brochures or other ways, of the risks it knows about its products?

MR. KOOPMANN: Objection. Go ahead.

A. You know, again, I -- I think that -- I

Page 123

think that there are regulations in place for a reason. And I think if you're asking me philosophically if the U.S. should change the way medicine is practiced in the U.S., I think that is a different conversation. The way things are in the United States, for better or worse, is that you have a patient and you have a doctor and you have a physician/patient relationship interaction. That's where patients come to get their information. That's where they come to get the diagnoses. They aren't going to random companies saying, You know, maybe I have high blood pressure, maybe I have cholesterol, you know, what should I do? What information can you provide me?

They go to their doctor and they say, you know, I'm here for my annual exam. And the physician will say, you know, We did the lab test and you have high cholesterol. We need to treat you.

So, you know, again, I don't -- I don't know how the company would go to all potential patients. And, again, I don't think companies need to. I think that, again, based on how medicine is practiced in the United States, it's physician to patient.

Page 124

BY MR. BRADFORD:

Q. This is a direct question.

Ethically, should a company warn patients or advise patients of the risks of its products that it knows about?

MR. KOOPMANN: Objection.

A. So, again, and as a direct answer, no -- nothing in medicine is without risk. And so if you're asking companies to provide risks, you should also ask them to provide benefits, but I don't think that that is the -- the obligation of a company.

I think a company should look at what they have. They should provide information to the regulatory bodies. I don't think that they need to be involved directly with patient care. I think that's a physician's job.

BY MR. BRADFORD:

Q. Are you familiar with patient brochures for the TVT, TVT-O and the Abbrevo?

A. I've looked at them, yes.

Q. Do you agree that the information in the patient brochures should be accurate?

A. I think that the information should be accurate, yes.

Page 125

Q. Do you agree that the information in the patient brochures should be thorough?

A. So, you know, we touched on this earlier.

You know, I think -- and going back to the very beginning conversation, it's not possible for any one document to have everything in it that it needs. I mean, documents aren't inherent living documents. And as more information comes out, I mean, you just -- I don't know how you would keep a document up-to-date always, you know? And so I think that the -- and I think I said this before, I think that the information for providers should include the information that's, you know, reasonably associated but not commonly known with the -- that -- that procedure, so...

Again, based on medicine in the U.S., I think a lot of that falls to the physician.

Q. The patient brochure is intended to be directed from the company to the consumer, the consumer being the patient, correct?

A. So are you talking about the IFU?

Q. No. The patient brochures.

A. So the patient brochures, again, I would look at patient brochures -- and this is not specific to Ethicon and this is just my opinion.

Page 126

You know, if you're providing information directly to a consumer, I would look at that as being marketing material. This is kind of how I would think that to be developed and distributed.

You're -- you have a product and you're -- you know, you're marketing it to potential people.

BY MR. BRADFORD:

Q. Do you think the information contained in this marketing material should be accurate?

MR. KOOPMANN: Objection.

A. I think it depends on how you define accuracy, but, yes, it should be. It should be.

BY MR. BRADFORD:

Q. Do you think the information provided in these marketing materials like patient brochures should be truthful?

A. Well, yes, I don't think that they should deceive people.

Q. Do you think if the company knows that there's a risk range of erosion for its midurethral slings, that it should put that risk range percentage in the patient brochures?

A. So, you know, again, I think that's a discussion for a physician and a patient as

Page 127

opposed to -- but, yeah, I mean, if patients want to -- to find the information, you know, I don't think that the onus is on the manufacturer to provide that to them.

You know, again, I know you're talking about erosions, but, again, as I discussed earlier, decisions aren't made in a vacuum. In general, the risks of midurethral slings are outweighed by the benefits, which is why they're considered the standard of care by all the national and international organizations. And so, counter, you know, part of being truthful is also not dissuading people to do something that would be beneficial. So if you're asking them to only put bad information in patient brochures, I don't think that's right either.

Q. My question is very direct.

A. Okay.

Q. Do you think that a company like Ethicon, if it knows of a range of percentages of the risk of erosion for its midurethral slings, that it should put that in its patient brochures?

MR. KOOPMANN: Objection. Go ahead.

A. So I think that my answer before was also direct. I think that it's not up to the company

Page 128

to provide all information for patients.

BY MR. BRADFORD:

Q. So that means no?

A. Well, so I think that they should provide balanced information.

Q. Sure. Fair and balanced?

A. If they're going to -- but again, I don't think that the -- I don't think that is on the corporation. I think that is on the physician to provide options for a sling, but also for a Burch and a pubovaginal sling and, you know, if I'm looking at a patient brochure and it tells me that the erosion risk is X, but I don't know what my other options are and whether or not the success rates are comparable between those, I think it's out of context and I don't think it's particularly beneficial, so...

Q. Have you seen a patient brochure as you described as a marketing piece that does not provide the benefit of the device?

A. I have seen many brochures that do not comment on alternatives. Most do not.

Q. "Alternatives," meaning other treatment options?

A. Correct.

Page 129

Q. I'm talking about the benefits of that device. For example, a patient brochure for the TVT or the TVT-O or the Abbrevo, those are quite good at talking about the benefits of those devices and what good can come to a woman's life from having them implanted, right?

A. Uh-huh. Okay.

Q. Would you agree with that?

A. I think, again, I think that -- I don't think that -- so speaking for myself personally as a consumer, I would not go --

Q. I don't mean to interrupt you, Doctor. And I haven't done this today and I'm very careful not to --

A. Sorry.

Q. -- but the question is specific as to the Ethicon midurethral sling brochures you've seen.

A. Yes.

Q. Would you agree that those sling brochures -- strike that.

Would you agree that the brochures for the Ethicon midurethral slings do a good job of advising of the benefits in the good things that can happen to women if they choose to have those devices implanted for their stress urinary

Page 130

incontinence?
A. I think that they do describe benefits, yes.
Q. Okay. And you would agree that they should also describe the risks in addition to describing the benefits to be fair and balanced, right?
A. So, I think that the patient should know what the risks are. Again, I know that we're talking about erosion. And so, you know, if you -- if you say that the brochure should include all risks of erosion, where does that stop, and how much information should be included and how much shouldn't? And why would erosion be selected as different than bleeding risk or infection risk or UTI risk?
Like, how would you determine what should and should not be included? You know, like, again, I think that that is the purpose of a physician. Do I provide these brochures to my patients? No. If they want them, they can get them, but, again, I think that my purpose as a physician when I provide patient education, it comes from the national societies.
Q. Doctor, I'm asking specifically as to the

Page 131

brochures that you've seen.
A. Yes.
Q. Okay. Do you think -- and this is simple. If they should, they should. If they shouldn't, they shouldn't.
Do you think that Ethicon, in addition to providing the benefits of its midurethral slings in its patient brochures, should also provide the risks including the percentage range of erosion for its midurethral slings?
MR. KOOPMANN: Objection. Go ahead.
A. So, again, I don't think it's possible for a patient brochure to include all pertinent information.
BY MR. BRADFORD:
Q. I'm asking specifically as to the risk range for erosions -- that's it -- that they're currently aware of.
MR. KOOPMANN: Same objection.
A. Yeah. My counterquestion would be, Why is an erosion risk any different than other risks associated with said device? Like, why -- how would you -- like, if you're going to fault someone for not including the information, they can't include everything, I don't think.

Page 132

So, again, I don't -- you know, if -- if -- if the company wanted to include that information, I think that would be fine. I think that would be up to them and to their, you know, marketing.
You know, from my perspective as far as patient care goes, I don't rely on the patient brochures and I don't direct patients to them. I would direct them to information that's going to come from, you know, an entity that will provide all information regarding multiple options.
BY MR. BRADFORD:
Q. I -- I'm going to ask again.
Direct question, specifically as to the risk of erosion. In the patient brochures for its midurethral slings, in addition to providing the benefits of the slings, should Ethicon provide the percentage risk range of erosion as well?
MR. KOOPMANN: Objection. Go ahead.
BY MR. BRADFORD:
Q. I'm going to ask this until I get a direct answer, and we may be here all afternoon. That's fine. I mean, I think the answer is no, but you won't say it. So --
A. But --

Page 133

MR. KOOPMANN: Objection. Go ahead.
A. So I don't think it's wrong for them to include it, but I don't think it needs to be included.
BY MR. BRADFORD:
Q. Fair enough. That's good enough. I don't care what your answer is. I just want it, right? So if your answer is yes, that's great. If your answer is no, that's great. I don't really care. I just want to know what it is. So I think you answered, so we can move on.
Do you agree that with the TVT device, there is the risk of foreign body response resulting in inflammation?
A. I think similar to any implant, there is a risk of reaction to.
In general, if you're asking my opinion about polypropylene, you know, the suture has been around since like the 1950s. That is what I choose to use for my Burch surgeries as well, and so, you know, I don't see a whole lot of inflammation.
Q. All right. I'm going to ask the question again.
For the TVT midurethral sling, do you

Page 134

think there's a risk of foreign body response resulting in inflammation?
MR. KOOPMANN: Objection. Go ahead.
A. So, you know, again, I think that in the short-term after surgery, any time anyone has surgery, there are risks of inflammation as part of the healing process. Long-term, when I've gone into take a mesh out, I don't see a lot of indication of inflammation or foreign body reaction.
BY MR. BRADFORD:
Q. You would agree that the Prolene mesh in the TVT is the same Prolene mesh that's in the TVT-O?
A. They're very similar, I believe, yes.
Q. Are they identical?
A. I don't know that. I don't know the chemical composite, but I presume them to be very similar.
Q. Do you understand that the Prolene mesh in the TVT is the same as the TVT Abbrevo?
A. It's a type 1 polypropylene mesh, yes.
Q. And do you agree it's essentially the same -- the mesh, itself, is the same whether it's the TVT, the TVT-O or the TVT-O Abbrevo?

Page 135

A. They are all very similar meshes, yes.
Q. Would you agree that for the TVT device, there's a risk of foreign body response resulting in extrusion, erosion or exposure?
A. Any time mesh is implanted, there's a risk of, you know, exposure.
Q. Would you agree for the TVT, there is the risk of foreign body response resulting in fistula formation?
A. So fistula formation is a risk from a sling placement. I don't think it's a risk from the sling itself. I think it's a risk from the implantation and the dissection as the sling is placed between the vaginal epithelium and the urethra.
Q. Do you agree with the TVT, there is the risk of mesh extrusion, exposure or erosion into the vagina or other structures or organs?
A. There is -- there is a risk of a mesh exposure in the vagina with placement of any mesh, yes.
Q. Would you agree that with the TVT, there's the risk of acute and/or chronic pain?
A. Yes. And as we discussed, I think that's similar with any surgery. All surgeries carry

Page 136

risk of pain.
Q. Would you agree that with the TVT, there is a separate, specific mesh-related risk for acute and/or chronic pain?
A. Mesh has its own inherent risks, yes.
Q. Which included acute or chronic pain?
A. Yeah -- yes. Pain can be associated with them, yes.
Q. Would you agree that the TVT comes with the risk of pain with intercourse, which in some patients may not resolve?
A. That is a risk.
Q. Would you agree with the TVT that there's the risk of neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area?
A. I think it depends on where the mesh is placed, but, yes, you know, again, I think we're splitting hairs on where the pain can be, but, yes pain is associated with slings or surgery.
Q. Would you agree with the risks I've just outlined come with the risk that they might require surgical treatment?
A. Yes, that is a risk.
Q. Would you agree that with the TVT,

Page 137

there's a risk of one or more revision surgeries that might be necessary to treat the adverse reactions or risks we've just talked about?
A. Yeah, I think that is true for the other antiincontinence procedures as well.
Q. But you would agree that there's a mesh-specific risk for one or more revision surgeries to treat the risk we've described?
A. Yes, mesh does have inherent risks.
Q. Would you agree that in cases in which the Prolene mesh needs to be removed in part or in whole, significant dissection may be required?
A. I think it depends on how you define "significant," but in order to remove mesh, it would need to be dissected free.
Q. Do you agree that with the TVT, there comes the risk of excessive contraction or shrinkage of the tissues surrounding the mesh?
A. That has not been my experience.
Q. Do you agree that Ethicon knew of all of the risks we just described -- strike that.
Do you agree that Ethicon knew of all of the risks that I just went through before the TVT originally went on the market?
MR. KOOPMANN: Objection.

Page 138

A. I know that I've looked at many of documents. I don't know that I've seen all. I don't know that I know everything that Ethicon may or may not have known at the time.

Again, what I've told you, you know, I base my knowledge on the medical literature, you know. And so I'm not basing things on a study that was done back in '93. I'm basing things on systematic reviews that were published more recently with the composite of risks and benefits. So I can't speak for Ethicon. I don't know -- I don't know what they did or didn't know.

BY MR. BRADFORD:

Q. When did you first consent a patient for the use of a midurethral sling?

A. It was probably in residency, 2006, 2007.

Q. Dr. Jeppson, I went through a list of risks just a minute ago.

To avoid having to go through -- well, let me strike that and try to lay a foundation.

Do the same risks apply for the TVT-O as well?

A. Yeah, any -- any -- yes. There are risks associated with midurethral slings that would be similar between retropubic versus transobturator.

Page 139

Q. Correct. And the list that I just went through, that would apply to the TVT-O as well?

A. My answers would be the same, yes.

Q. And is the same true for the Abbrevo, that the risks would be the same for the TVT or Abbrevo?

A. They would be similar, yes.

Q. Well, similar is not the same so what would be different regarding the TVT-O?

A. The TVT-O versus TVT-O Abbrevo; is that what you're asking me?

Q. I'm sorry. That's horribly unclear. I apologize.

I'm just going to go through it, Dr. Jeppson.

For the TVT-O, do you agree that there's the risk of foreign body response resulting in inflammation?

A. Yeah. Again, as we discussed for the retropubic sling, it depends if you're talking acute right after the time of surgery versus remote from, but any time a foreign body is placed, there is potential for reaction.

Q. And do you agree for the TVT-O there comes the risk of extrusion, erosion and exposure?

Page 140

A. So, yeah, again, there are risks inherent to mesh, which include exposure.

Q. And would you agree that with the TVT-O, there comes the risk of a foreign body response resulting in fistula formation?

A. Again, I don't think that it results in fistula. I think that fistula have been associated with. It seems that most of the publications I have seen in personal experience is based on where the mesh is placed as opposed to the mesh causing the fistula, but it is a possibility.

Q. Doctor, do you agree that the TVT-O comes with the risk of mesh extrusion, exposure or erosion into the vagina or other structures or organs?

A. Yes, there's risks associated with mesh, yes.

Q. Do you agree that the TVT-O comes with the risk of acute and/or chronic pain?

A. That is a risk of any surgery, yes.

Q. And would you agree that there's the mesh-specific risk with the TVT-O of acute and/or chronic pain?

A. That is a risk, yes.

Page 141

Q. Do you agree that the TVT-O comes with the risk of pain with intercourse which in some patients may not resolve?

A. That is a risk, yes.

Q. Do you agree with the TVT-O, there comes the risk of neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area?

A. Again, similar to my prior statement, it depends on where the mesh is placed, but there is a risk of pain with mesh placement.

Q. You would agree that the TVT-O comes with the risk of adverse reactions that might require surgical treatment?

A. Repeat operation is a risk of really any surgery, but in this case, that is also true.

Q. And you would agree that with the TVT-O there comes the risk of one or more revision surgeries that may be necessary to treat the adverse reactions or risks we've just gone through?

A. Yeah, and, again, I would say it's similar to Burch or pubovaginal sling. Those risks are the same. They all carry risk.

Q. You would agree that it is easier to

Page 142

remove a suture than a woven synthetic mesh that has tissue integrated through it?
MR. KOOPMANN: Objection.
A. Again, I think that I said this before, but not necessarily; depends on where the suture is placed and how it was placed. It depends on where the mesh is and where it was placed and how, but it's not necessarily harder. Sometimes it can be easier.
BY MR. BRADFORD:
Q. You would agree with the TVT-O comes the risk of, in cases in which the Prolene mesh needs to be removed in part or whole, significant dissection might be required?
A. Again, it depends on how you define significant, but the mesh would need to be dissected free to be removed.
Q. And, Doctor, do you agree with the TVT-O, excessive contraction or shrinkage of the tissue surrounding the mesh is a risk?
A. And, again, I have not really seen that.
In the medical literature, there is a report of a, you know, mesh shrinking maybe 10 percent. Pubovaginal slings shrink a lot over the course of the first few months to year. And so

Page 143

slings, midurethral slings shrink much less than pubovaginal slings.
Q. I hate to do this, but I'm going to have to ask you the same questions for the Abbrevo since there's multiple products. I would rather not, but somebody is going to yell at me in the Abbrevo case if I don't do it, okay?
A. That's fine.
Q. Doctor, you would agree with the TVT Abbrevo that there's the risk of foreign body response resulting in inflammation?
A. Again, it depends on if you're talking about acute or chronic. At the time of surgery, there's always a risk of inflammation that kind of goes with surgery. Long term, there is a risk with any foreign body.
Q. Do you agree with the TVT Abbrevo, there comes the risk of foreign body response resulting in extrusion, erosion or exposure?
A. Again, you know, there is a risk inherent with mesh that there can be, you know, erosion or exposure when mesh is placed.
Q. With the TVT Abbrevo, there comes the risk of foreign body response resulting in fistula formation?

Page 144

A. And, again, I'm not certain that the fistula formation is related specific to the foreign body reaction. I think it's based more on where the device is placed, but it is a risk at the time of the sling surgery.
Q. And you would agree regarding the TVT Abbrevo that it comes with the risk of mesh extrusion, exposure or erosion into the vagina or other structures or organs?
A. Again, as we discussed, there are risks inherently associated with mesh and erosion is one of those.
Q. You would agree with the TVT Abbrevo, there comes the risk of acute and/or chronic pain?
A. Yes. There's a risk of pain with any surgical intervention.
Q. And regarding the TVT Abbrevo mesh, there's a mesh-specific risk of acute and/or chronic pain, correct?
A. That is correct. There's a mesh -- there's a risk inherent to mesh, yes.
Q. And you would agree with the TVT Abbrevo, there's the risk of pain with intercourse which in some patients may not resolve?
A. Again, inherent to mesh, there are risks,

Page 145

yes.
Q. You would agree with the TVT Abbrevo -- strike that.
You would agree with the TVT Abbrevo, there's the risk of neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area?
A. Again, it depends on where the mesh is placed, but mesh does carry inherent risks as does any surgery.
Q. Doctor, you would agree that with the TVT Abbrevo, there comes the risk that those adverse reactions I just mentioned might require surgical treatment?
A. And, again, yes, that is a risk of any surgery as a possibility of repeat surgery.
Q. And there's a mesh-specific risk as well with the TVT Abbrevo?
A. There is a mesh-specific risk, yes.
Q. Doctor, would you agree that's there's -- strike that.
Doctor, with the TVT Abbrevo, do you agree there's the risk of one or more revision surgeries may be necessary to treat the adverse reactions or risks we've just gone through?

Page 146

A. And, again, I would agree with that, but also state that that is also possible with any surgical intervention.
Q. But you would agree there's a mesh-specific component to that as well, correct?
MR. KOOPMANN: Objection.
A. And, again, mesh does have inherent risks.
BY MR. BRADFORD:
Q. Including one or more revisions surgeries, correct?
A. This is a possibility.
Q. You would agree that with the TVT Abbrevo in cases in which the Prolene mesh needs to be removed in part or in whole, significant dissection may be required?
A. Again, I think it depends on how you define "significant," but the mesh would need to be dissected free to be removed.
Q. And you would agree with the TVT Abbrevo that there's a risk of excessive contraction or shrinkage of the tissue surrounding the mesh?
A. And, again, similar to the others, the midurethral slings, I have not seen that.
Again, in the literature, it's a 10

Page 147

percent -- the mesh contracts by 10 percent over the course of the first year, which is significantly less than pubovaginal slings, which are set much more loosely because they do contract so much.
Q. Doctor, do you understand or know that Ethicon knew of the risks and adverse reactions we've gone through regarding the TVT-O before the time the TVT-O was launched?
MR. KOOPMANN: Objection.
A. You know, again, I've seen some internal documents from Ethicon. I do not remember everything. I'd have to go back and look and I don't pretend to know everything Ethicon did or didn't know at the time.
BY MR. BRADFORD:
Q. Doctor, do you agree that Ethicon knew of all the risks regarding the TVT Abbrevo we just went through before the time of launch?
MR. KOOPMANN: Objection.
A. You know, again, I don't know what they did or didn't know.
BY MR. BRADFORD:
Q. When you've removed midurethral slings or portions of midurethral slings in surgeries, is it

Page 148

fair to say that you've looked at those -- you've looked at what was explanted, correct?
A. I always look at what I remove, yes.
Q. Right. And do you look at it with a microscope or do you just do a gross look with the naked eye?
A. I do gross and send it to pathology.
Q. Right. And it's pathology's job, it's their job to look under the microscope and describe what's there?
A. You know, so that is a pathologist's job is to look at pathologic specimens and then to say what they are. And I don't make it a habit to look under the microscope to see what's there. I have looked in publications to see, you know, what's reported in that, but, yeah, I don't -- I don't think that I need to look under the microscope to know that it's mesh.
Q. Is it fair to say that you would need to look under the microscope to see whether the mesh has degraded?
A. I think that if you were to determine degradation, I think you probably need a scanning electron microscope, not just a typical light microscope that would be in most universities'

Page 149

labs.
Q. Fair enough.
So is it fair to say that to be able to see degradation on a piece of excised mesh and tissue, you would need an electron microscope?
A. I think that if -- so what I think is that you can look at published literature to see what happens to the mesh. I don't think that every specimen would need to be analyzed.
Q. Yeah. And let me tell you why I'm asking you these questions, okay?
A. Okay.
Q. Because every time we take one of these doctors who's taken this out, they get a series of questions from Ethicon lawyers to say, did you see any degradation, did you see banding, did you see roping, fraying, curling, et cetera, et cetera.
So -- and I'm asking you these questions because I want to know your opinions as to whether or not you see that with the naked eye or whether you would need to actually look under an electron microscope to see those things, okay?
A. Yeah.
Q. So I'm not trying to dig into the literature on this.

Page 150

A. So I think that the surface -- like, to see degradation at the surface structure, you would need a scanning electron microscope. I think to see the -- the roping, curling, fraying, I don't think that you would need a microscope to see that. I don't think you'd need a scanning electron microscope to see that.

I think some of that could be visualized with the naked eye. I think some of that could be visualized just by histologic specimens, you know, by trans -- you know, by dissection evaluation, but I think that I have not seen a lot of that when I've removed. I don't really see roping and curling and fraying when I'm taking mesh out. It seems to be fairly well-incorporated, which is what it's supposed to do.

Q. All right. Are you aware of how the -- strike that.

Are you familiar with the terms laser cut and mechanically cut?

A. Yes.

Q. Okay. I'm going to ask you some questions about that.

When did you first become aware of that the TVT-O -- strike that.

Page 151

Do you have an understanding as to whether or not the TVT-O device at different time periods was laser cut or mechanically cut?

A. So prior to initiating my relationship with Ethicon, I did not know.

Subsequent to that time, I am aware that the TVT-O Abbrevo is laser cut and always has been and that the other options have transitioned over time. Again, looking at the medical literature, the, you know, large randomized controlled trials funded by the NAH as well as the systematic reviews based on my understanding of when that transitioned, there is not a significant difference in rates of complications based on whether a mesh was laser cut or mechanically cut.

Q. All right. Doctor, so before Ethicon hired you to become an expert in this case and you were provided internal information, you had no idea that the TVT-O at different time periods came with laser cut or mechanically cut, correct?

A. I don't think it's clinically relevant.

Q. I appreciate that opinion, but --

A. So -- so -- so --

Q. My question is more direct than that.

A. So I had heard of the two different

Page 152

types, but I didn't know which was which with which sling. Did that answer the question?

Q. A little bit. Let me ask it again so the record's clear.

Before you were hired as an expert for Ethicon, you did not know which meshes were laser cut versus mechanically cut, correct?

A. Correct. I don't think, yeah, I don't think it's clinically relevant and I did not know.

Q. Based upon your review of internal Ethicon documents, was Ethicon concerned about the difference between mechanically cut mesh and the laser cut mesh?

A. I think that they had -- they wouldn't have changed from one to the other or back if they didn't have reason to, so I'm sure there was some sort of internal dialogue that prompted that. And I think that some of that came from physician feedback based on, you know, kind of what they had seen at the time of opening the devices.

Q. Do you have an understanding as to whether or not laser cut mesh is stiffer than mechanically cut mesh?

A. You know, again, this relates to the question you'd asked me before about, you know,

Page 153

percentiles or proportions. You know, stiffness is relative. So do I think that there's a clinically-significant difference in the stiffness between a mechanically cut and a laser cut? I don't think it clinically matters.

If you were to look at the, you know, like, engineering profiles and, you know, the -- you may see the difference, but, again, I don't think that it's clinically -- I don't think that it clinically matters.

Q. Excluding clinical significance for the purposes of this question, you would agree that laser cut mesh is stiffer than mechanically cut mesh?

A. Yeah. I think that there is data to show that laser cut is slightly stiffer than mechanically cut, but, again, I would say that I don't think that it matters.

Q. Would you agree that with mechanically cut mesh comes the risk of particle loss?

A. So at the time of surgery when I've opened mechanically cut meshes, sometimes you can see some -- some particle loss there. I don't know, you know, but, again, I've not seen any literature that reports on those particles causing

Page 154

any issue or any problem.
Moreover, once the device is open, any particle loss that's there would not be implanted in the patient because it would stay on the back table.
Q. If a mechanically cut mesh was subject to particle loss within the packaging itself, would you agree that there could also be particle loss once implanted?
A. You know, again, I would say that based on published literature pre- and post-mechanical versus laser cut, there is no clinical data to substantiate that and so I would say it probably doesn't matter.
Q. Are you aware of any study that -- strike that.
Are you aware of any literature or study which has looked at the difference between mechanically cut TVT-O and laser cut TVT-O?
A. I know that I have seen studies on that, yes.
Q. Specifically looking at the clinical differences between the two?
A. So, again, the TVT-O Abbrevo has always been laser cut.

Page 155

Q. Sure. I'm sorry. Let me re-ask my question. This was specifically -- this was specific as to the TVT-O.
A. So, again, what I was saying is pertinent to this though because the TVT-O Abbrevo has always been laser cut. So, again, if you're looking at studies pre- and post-mechanical to laser, I am not aware of any clinical trials that show any significant difference.
Are there studies that look specifically at the composition of the slings regarding stiffness, et cetera? Yes, I'm sure that there are, but, again, I don't think that they matter clinically.
Q. Are you aware of any studies regarding the clinical significance of particle loss from mechanically cut mesh?
A. Again, I know that it has been studied and, again, I remember seeing some internal documents. I'd have to refresh my memory on exactly what they said. But, again, I base my medical knowledge on a composite of information including systematic reviews like, you know, Cochrane reviews or other reviews and when you look back at the adverse events or the risks

Page 156

associated with slings, it doesn't come out that, oh, they changed from mechanical cut to laser cut or from laser cut to mechanical cut or this one had particle loss and, therefore, the risks are different.
Clinically, they behave the same. So from a -- I am a clinician. From a clinical perspective, I don't think it matters. From a scientific perspective, if you want to get into the science and everything and look at all the basic science stuff, you know, it's interesting, but I don't think that it impacts patient care.
Q. Sitting here today, do you recall the name of any study specifically that compared TVT-O mechanically cut versus TVT-O laser cut?
A. I don't remember names.
Q. Are you aware of a study comparing the erosion risk between TVT-O mechanically cut versus TVT-O laser cut?
A. So, again, I have probably seen studies regarding that, you know, and this gets back into what we were discussing earlier regarding level of evidence, which we haven't gotten back to.
There -- the medical -- the composite of medical literature, it grows at such a rapid rate,

Page 157

it's impossible to keep up with everything. So could there possibly be some case series or some small comparative cohort study that demonstrates difference? It's possible.
Again, looking at level 1 evidence, the big RCTs and the big systematic reviews, that has not been an issue. So, again, I would say it's not clinically important.
Q. Do you agree that if a company has two different products that both do the same thing and have the same efficacy but one has a greater risk than the other that the company should only offer doctors the product with less risk?
A. I think that's a very simplistic view. Having heard many physicians discuss these issues, different surgeons feel that different products behave differently in different hands. So, again, this gets back to the question of should the company provide risks? I think that risks are somewhat dependant upon the person implanting them. So, you know, like, for example, with the Caldera sling that I'm currently using, they have several different trocar types not because one is safer or more dangerous but to accommodate the desires of the surgeon based on their experience

Page 158

and training.
So, you know, again, I would not say that they should remove -- so, again, from an ethical perspective, you know, you want to provide the best care to patients. I think that that can be accommodated differently by different providers based on different products.
Q. So the answer's no?
MR. KOOPMANN: Object to form.
A. Well, but the question you asked is, you know, do I think that companies should provide something unsafe? Well, I don't think that the company should ever do that.
BY MR. BRADFORD:
Q. Let me ask my question again.
Would you agree that if a company has two different products that both do the same thing and have the same efficacy but one has a greater risk profile than the other, the company should only offer doctors the product with the less risk?
MR. KOOPMANN: Objection.
A. But, again, I think that's a very simplistic view. So what I may think is the best may not be what my colleagues thinks is the best and I've had those discussions with them. So,

Page 159

again, I think that it's up to the surgeon to know what device they're using and what the risks are associated and have those discussions with their patients.
You know, if you want it pure black and white that one is good and one is bad, well, they shouldn't use the bad one, but medicine is not that way. Medicine, there's a lot of gray. So again, I think that physicians should know what they're using when they implant it.
BY MR. BRADFORD:
Q. So the answer is no?
MR. KOOPMANN: Objection.
A. Again, I --
BY MR. BRADFORD:
Q. How about the answer is yes, no, or I can't answer the question? Maybe that's a better way to do this. I mean --
A. But I think I did answer the question.
Q. I know, with a philosophical point of view that's not answering the question.
I mean, look, I've told you, I don't care whether you answer yes, no, I don't know, but the question is direct. I'm going to ask it one more time.

Page 160

If a company has two different products that both do the same thing and have the same efficacy but one has a greater risk than the other, one has a greater risk profile than the other, do you agree the company should only offer doctors the product with the lesser risk profile?
MR. KOOPMANN: Objection.
A. So, you know, I know you want a yes or a no or I can't answer, but I don't think any of those are the answer. I think that when I offer products or surgeries to patients, there are different surgeries that could be better for one patient versus another. So should I not offer that particular surgery to anyone? I don't think so.
So, you know, again, I think that -- I understand that you're painting it as black and white, but the practice of medicine is not that and so I guess if you're pushing and making me answer, I guess I would say I can't answer that, but I would say that I feel that I have answered it and I think that it depends on the product and the patient and the physician.
BY MR. BRADFORD:
Q. I'm not asking about the surgery. I'm

Page 161

asking about the device itself.
A. But the devices are surgeries. They are -- I mean --
Q. Okay.
A. -- you can't -- you can't -- we're asking about surgical implantation of a device. It is a surgery.
Q. Do you agree that a suture is a medical device?
A. So I just had this conversation in the OR on Monday. I think that suture is -- so I don't list suture as a device when I do the operative report. I do say what I use. I say if it was a Vicryl or a Monocryl or a silk or whatever.
I think a device is typically more involved than a simple suture.
Q. You wrote an abstract comparing Abbrevo to TVT-O, correct?
A. Yes.
Q. And in that abstract, the conclusion was that the Abbrevo had the same efficacy as the TVT-O, correct?
A. It showed similar efficacy, yes.
Q. But that the Abbrevo was safer in that the Abbrevo did not cause the risk of groin pain

Page 162

that came with the TVT-O because it's shorter and did not enter as far into the obturator -- the transobturator space, correct?

A. It didn't traverse quite as many muscles, about a 10 percent difference. I think it was like 9 percent for the full length and like 1 or 2 percent for the short, but this is a retrospective study comparing two different slings but retrospectively, and I think -- I can't remember how many patients we had. It was like maybe 100 per arm or something like that over the course of seven or eight years.

So, you know, again, does -- you know, if I were to -- and I think I told you this before, if I were choosing, you know, just based on my choice and not on, you know, what the hospital had contracted, I like the TVT-O Abbrevo. I think it's a great product.

Would I base all of the medical knowledge on that particular publication? I would not. I would look at the composite, you know, and literature. So, again, I like the TVT-O Abbrevo. I don't think that means that the TVT-O is a bad product.

Q. Do you think the TVT-O Abbrevo is as

Page 163

effective as the TVT-O?

A. In that study that we looked at, we found similar efficacy.

Q. Outside of that study?

A. In general, I think that they are similar efficacy, yes.

Q. Would you agree that TVT-O Abbrevo is safer?

A. I think that if you're looking at the issue of groin pain, again, our studies showed that there was less groin pain associated with the Abbrevo than with the full length.

Q. Sounds like you're -- I hate to say this -- but minimizing the significance of your own study because it was a retrospective study over only 250 patients; is that correct?

A. I don't think I'm minimizing it. I think that I'm interpreting the data, which is what I do as a physician. You would never -- I don't think you would find a physician who would say the retrospective study provides as much information as a systematic review, for example, but it does depend on which outcomes you're looking at. And sometimes retrospective studies or case controlled studies can, but in general, I would not -- I

Page 164

don't base all of my medical knowledge on anything even if I've published it because it's a composite.

Q. How long a study does it take for you to consider it to be long-term study?

A. So -- so I think that's an arbitrary question. I don't know if you're asking me because that particular study --

Q. I'm not -- it just happened to be my next question. I'm not criticizing you about the study or your work.

A. That's okay. I'm not -- I'm not defensive.

Q. I'm not suggesting that's a long- or a short-term study. It was the next question so put that study away. In general, how long --

A. So I think that -- I think that what is considered long-term or short-term depends on the outcome you're looking at. If you're looking at perioperative outcomes like bleeding and things like that, a long-term study is probably going to be two weeks. If you haven't had bleeding by weeks, you're probably not going to have bleeding from the surgery. Whereas with, you know, other, like, long-term outcomes, I would want to see

Page 165

things at, you know, a year to two years, five years.

I'd love to see studies that follow patients out 20, 30 years. Those are very expensive and hard to find, but in general, in my mind, short-term, I would say probably somewhere 6 to 12 months. Long-term would be beyond that, but it would depend on the specific outcome that you're asking me about.

Q. How long should a company study a product before it launches it?

A. So I don't think that's up to me. I think that's up to Federal regulators and I think that they have mechanisms in place to determine that. And, again, as I've said, I think the companies should follow the Federal mandates.

Q. As an expert in this case and a teaching physician at the University of New Mexico, do you think a company should launch a midurethral sling without it being studied?

MR. KOOPMANN: Objection. Go ahead.

A. So if we're talking specific about midurethral sling, the way that things were set up back in the '90s and early 2000s was to demonstrate that the device had similar efficacy

Page 166

to a predicate device and if that could be demonstrated, it could go to market.

So, again, I'm suggesting that companies should follow the mandate of the -- the government organizations to which they subscribe. I don't know exactly what was done in Scandinavia or in England or in Europe, but -- to get approval for the same slings. So, again, I would say that if you're going to market and sell a product in a nation, you should follow the mandates of that government. And, again, I don't think it's fair to say that they didn't have any data. If we're talking specific about the sling, there were predicate devices and they followed the mandates of the time.

BY MR. BRADFORD:

Q. Do you know what the predicate device was for the TVT?

A. I've heard. I don't -- I don't remember off the top of my head. I know I read it as a -- as a fellow and probably as a resident. I didn't review it again for this.

Q. Do you believe that the TVT was substantially similar to this claimed or alleged predicate device?

Page 167

A. So as with a lot of medical -- pardon me.

With a lot of pelvic mesh, many of the predicate devices were subsequently removed from the market and so I do know that. But, again, I am not here to criticize nor to substantiate the way the government mandated things should be done at the time. And for the midurethral sling, I think it's turned out quite well. There's a lot of data to show that it's safe and effective. You know, we have 25 years of data. Would that be how I would design things if I were to do something now? I probably wouldn't, but, again, things are different now.

Q. You're here as an expert in this case to talk about the TVT-O device, correct?

A. Yes.

Q. And to talk about the TVT-O device from its beginning to present, right?

A. Uh-huh.

Q. Is that correct?

A. Yes.

Q. And to talk about the safety of the TVT-O device from its beginning to the present, correct?

A. Uh-huh, yep.

Q. And the efficacy of the TVT-O device from

Page 168

its beginnings to the present?

A. Yes.

Q. And the same is true for the TVT-O and the Abbrevo, correct?

A. Yes.

Q. Okay. So I'm going to ask the questions again not -- strike that.

Do you have an opinion one way or the other as to whether a company should have performed a randomized controlled trial on a product before it launches it?

A. Again, my feeling is the same. I think that a company should follow the requirements to get something to market. And if the requirements by the governing organization are that it requires a randomized controlled trial, then that's what it needs.

If you were to look at the way most things get to market, most things don't start with randomized controlled trials. Most things start with animal studies and then very small case series and you work your way up through safety and then get things to market, so...

Q. So the answer is no?

A. I don't think that -- I don't think an

Page 169

RCT is always required to get something to market, no. I think that they should follow whatever the requirements are.

Q. And if the requirements -- if a product can come to market without an RCT, you're okay with that?

A. If a product has gone through the regulatory board and has met the requirements to go to market, then I think that it can go to market.

Q. I'm cutting out the regulations, any FDA requirements, any of that stuff, okay. I'm asking you as an expert in this case and as a teaching professor at the University of New Mexico, do you think a company should be able to launch a product without performing randomized controlled trials?

MR. KOOPMANN: Objection. Go ahead.

A. Again, I -- I don't know how to answer it differently.

I don't think that a randomized controlled trial is always needed to get something to market. That doesn't mean that no testing should be done and there are cases where an RCT should be done, but I don't -- I can't provide blankets statements that would say, yes, always

Page 170

or, no, never because the truth lies in the middle.
BY MR. BRADFORD:
Q. Are you aware that the predicate device for the TVT was the ProteGen sling?
A. I've heard of ProteGen sling, yes.
Q. And were you aware that the ProteGen sling was removed from the market?
A. Yes.
Q. Do you think that a device should be allowed to be marketed -- strike that.
Do you think that a device should be brought to market when it's predicate device was removed from the market for safety and efficacy issues?
A. So I would say that hindsight is always 20/20 and if you're looking at things from a historical perspective, again, I would probably design things differently.
I would say that at the time that the mandates were met. And so, you know, if that's not how things should be done, and they should be changed moving forward, and that is what has happened.
Q. I'm going to ask you some questions from

Page 171

your report, first on the midurethral sling report for the TVT, the TVT-O and Abbrevo.
A. Okay.
Q. Before I do this, I want to go through the CV a little bit.
MR. BRADFORD: I'll mark it as the next exhibit.
(Exhibit Jeppson T-10, Dr. Jeppson's Curriculum Vitae, marked for identification.)
MR. BRADFORD: To save you some time, I'll go ahead and mark the thumb drive also.
(Exhibit Jeppson T-11, Thumb drive, marked for identification.)
BY MR. BRADFORD:
Q. I've marked Dr. Jeppson's CV that he provided as Exhibit T-10 and the thumb drive that they brought with them as T-11 and I think we'll be taking a break now.
MR. KOOPMANN: And just for the record, before we take a break, there's a password for that thumb drive and I've got it here.
MS. BAGGETT: You don't want to read it on the record, I don't think. We'll take a picture of it.
MR. KOOPMANN: Yeah.

Page 172

(Whereupon, a brief recess is taken from 1:24 p.m. to 1:44 p.m.)
BY MR. BRADFORD:
Q. You would agree in serving as an expert witness in cases like this that you have an obligation to look at all information relevant to the topic or subject, correct?
A. Yes.
Q. And that you have an obligation to look at information that both supports your positions and does not support your positions or opinions, correct?
A. I would want to have a balanced view, yes.
Q. Right, and that's my next question. You agree that in serving as an expert in cases like these, the goal and what you're required to do is come to fair and balanced conclusions considering all data made available to you?
A. So I agree with that to a certain point, you know, and, again, I alluded to this or maybe I said it expressly. Not all information carries the same weight.
Q. Sure.
A. Right? And so part of being fair and

Page 173

balanced is providing adequate weight to different forms of evidence.
Q. Fair enough.
Regarding medical literature, is it important to you to consider whether the study or literature article are funded?
A. Certainly.
Q. And is it important for you to consider who is funding articles or pieces of medical literature?
A. Yes.
Q. And is it also important to you to consider if the authors have any financial incentive regarding medical device if they do research upon it and publish that research?
A. Yes. When we do systematic reviews, there's many different types of bias, but certainly those are types of bias or potential biases.
Q. Do you have an understanding as to the pore says of the Prolene mesh used in the TVT, TVT-O and Abbrevo?
A. Yes.
Q. What is that?
A. It's roughly 1.3 millimeters or 1300

Page 174

microns.
Q. And do you have an understanding as to the weight of the Prolene mesh used in the TVT, TVT-O and TVT Abbrevo?
A. I've seen that number. I can't remember that offhand, but I have seen that.
Q. Is the weight of the Prolene used significant to you?
A. I think that there's an interest there, again, in kind of the geeky, nerdy theory sort of way, but, again, as I was discussing earlier, really what matters is the clinical implications and the clinical outcomes. And so I don't know that I -- you know, a practicing physician needs to know how much a certain segment of mesh weighs to know whether or not it's effective based on trials.
Q. Do you think pore size is significant regarding meshes used in midurethral slings?
A. I think the pore size is important in that it's been demonstrated that when pore sizes become too small, complications become higher and that's why there's type 1 mesh, type 2, type 3, type 4.
Type 1 mesh is when the pore size is

Page 175

greater than 75 microns. Type 3 or, you know, as it gets below 10 microns is when you get worried about the host immune, you know, the -- like microphages, that stuff, not being able to get into the mesh to fight infection. All the meshes we're discussing are type 1 polypropylene, which are much higher than the requisite 75 microns.
Q. Do you consider the Prolene mesh used in the TVT-O to be a heavyweight mesh?
A. I do not.
Q. Do you consider it to be a lightweight mesh?
A. I consider it to be a type 1 mesh.
Q. And that's from the Amid classification?
A. Correct. It was published in '97 or '98.
Q. In your review of internal Ethicon documents, did you come across anywhere the company referenced the Prolene mesh used in the TVT, TVT-O and Abbrevo as heavyweight mesh?
A. I did see documents that referred to it that way, yes.
Q. Do you disagree with those documents?
A. I think that when looking at documents, it's easy to take things out of context. I don't particularly care what one, you know, researcher

Page 176

said to another researcher regarding internal documents. If you have a device that weighs, you know, 1 gram and you have another device that weighs .9 grams, you can say one was heavy and one was light, right? It's all relative, but, again, from a clinical perspective, I don't think that matters.
Q. In your review of the corporate depositions you were provided, did you come across any of those where Ethicon scientists said that the Prolene mesh was heavyweight?
A. Yeah, I remember seeing internal documents, yes.
Q. Do you remember seeing any deposition transcripts where the scientists were asked about it and testified that the Prolene mesh was heavyweight?
A. I remember seeing that. I don't recall if they were in depositions or if it was in internal e-mails, but I know that I saw it. I'd have to go back and look at the documents to refresh my memory.
Q. Do you recall seeing any internal documents where the Prolene mesh was referred to as small-pore?

Page 177

A. That I don't recall. And if they did, I would disagree with that. Again, just based on the Amid classification of greater than 75 microns, I think larger than that's a type 1 polypropylene mesh.
Q. Do you recall in your review of the internal documents any documents referring to Prolene mesh as microporous?
A. So I don't recall that, no.
Q. Do you recall in reviewing the depositions you were provided from the Ethicon corporate witnesses, Ethicon scientists or other high-level people referring to the Prolene mesh as small-pore?
A. I remember weight, heavy and light. I do not remember porosity being discussed. I'd have to go back and review that.
Q. Do you agree that the TVT-O device comes with the risk of -- strike that.
Do you know whether or not the IFU for the TVT-O, when it came on the market, described the risk of groin pain or leg pain?
A. I've looked at the IFUs. I looked at an earlier version and a more updated version, but I don't recall offhand. I'd have to go back and

Page 178

look.
Q. Let me -- Doctor, if the TVT-O IFU, when it came to market, did not reference the risk of groin pain, should it have?
A. So as we discussed earlier, you know, I think the -- I don't think the purpose of the IFU is to provide physicians with all possible outcomes or all possible complications.
You know, again, I think that if there are things that are, you know, reasonably or somewhat associated with, that would be worth mentioning.
Again, I would -- I would say that they should follow whatever the government mandates are for the IFU. Again, just talking to people, I think most physicians don't really reference the IFU very often, if they ever read it at all.
Q. Doctor, do you recall when the first TVT-O randomized controlled trial was published?
A. I don't recall. The transobturator sling, it was, I think, first approved in 2001. TVT-O, the first publication, I'd have to look. My guess is probably 2005 or '6 would be my guess, but I don't know that.
Q. If the risk of groin pain is not in the

Page 179

IFU and there's no publications about it, how are doctors supposed to know that if the company doesn't tell them?
A. So I think that with risks with any surgery, not everything is always known at the outset of a given surgery. And that is true historically for all surgeries.
I think that part of using new devices is, you know -- part of studying new devices is to find out what the outcomes are. I think, you know, again, we've talked about this, and I don't know whether or not Ethicon had data to report that they knew specifically about groin pain and if they had the known rates of that. But, again, I don't think that it's up to the -- the company to provide all data to physicians.
Q. Specifically as to groin pain with the TVT-O, I mean, that's a problem, right? If the device comes on the market and there's no warning of groin pain and it takes some time for that to become published on, like, that's a problem for those doctors to use it during that time window and a problem for the unfortunate patients who are implanted and don't know that, right?
MR. KOOPMANN: Objection.

Page 180

A. So I think that that is true for any medication or device, which is why you have medications that go through all the premarket data and get to market and then later are recalled.
It's not possible to know everything from the outset. I would say that, you know, I wish that there were procedures that did not have risks or complications, but that is not the case. And so, again, you know, I know that you're focusing on the -- the groin pain issues, but, again, when looking at antiincontinence surgeries, the composite must be weighed and other surgeries also have complications.
BY MR. BRADFORD:
Q. Groin pain is specific to the TVT-O, correct?
A. Based on where it is placed, there -- it does have a risk over retropubic slings, yes.
Q. Do you think patients should be used as guinea pigs during that window of time between launch and when the literature catches up if the company doesn't warn of the risk?
MR. KOOPMANN: Objection.
A. So I think that the term "guinea pig" is a sensationalized term. I think that if you don't

Page 181

have medical progress, we would all be stuck in the 1800s without anesthesia and without appropriate surgeries. So to a certain extent, the practice of medicine is a practice. Unfortunately, it is -- it is not completely precise and, unfortunately, there have been mistakes made. You can look back at history to see evidence of those.
And I don't think that patients should be used as guinea pigs, but I also don't think that patients should forego useful treatment options in fear of not providing -- in fear of possible harms.
BY MR. BRADFORD:
Q. The retropubic -- the TVT retropubic was already on the market when the O came out, right?
A. It was.
Q. Should companies develop products just for market share as opposed to patient efficacy?
MR. KOOPMANN: Objection.
A. So I don't know that the devices were developed specifically for market share.
If you're looking specific at the TVT-O, the Monarc had already been on the market, I believe, for a couple of years, maybe two or three

Page 182

years before they got the TVT-O to market. So there was already a device on the market that was similar to.

As a practicing physician, there are times when I would prefer a transobturator sling over a retropubic sling. And so, again, there are benefits to both. And so, I don't -- I guess I don't know how to answer that question. I think both -- both procedures are good procedures and they need to be selected in appropriate patients.

BY MR. BRADFORD:

Q. Do you -- did Ethicon ever provide you any documents that outlined why it developed and brought the TVT over market?

A. I don't recall seeing those. I may have seen them. I don't recall.

Q. If there were documents where Ethicon stated it brought that device to market because it was losing market share to its competitors' obturator devices, would that surprise you?

A. No. I don't think that would surprise me, but I don't know that it was losing the retropubic market. It was losing the transobturator market would be my suspicion and I would have to go back and review those documents.

Page 183

And as is the case with many corporations not simply in medicine, if Apple has the best phone, well, Google will probably get involved or Microsoft may. You know, market forces are at play, but I wouldn't say that's to the detriment of patients. It's providing options.

Q. Do you agree that companies such as Ethicon should put patient safety first?

A. So I think that patient safety should always be an important consideration.

Q. Do you agree that companies such as Ethicon should always put patient safety first?

A. So, again, when we're talking about safety, I presume you're discussing the composite of risks and benefits, right? So, you know, again, I agree with being safe, but there are inherent risks or benefits to any surgery or any procedure. And so, you know, there is -- in the history, there is no -- well, I can't say that. I don't like to make absolutes.

It is unlikely that there is anything that only provides benefit and has no risk and that would be true here as well.

Q. Stress urinary incontinence is not life threatening; is it?

Page 184

A. It is a quality-of-life issue.

Q. Right. And the implantation of midurethral slings for stress urinary incontinence is an elective procedure, correct?

A. It is elective. It's not mandatory.

Q. In your report you reference regarding duloxetine, that it's approved for use in Europe, but considered off-label for treatment of SUI in the U.S. Do you recall that?

A. Yes.

Q. Do you have an opinion as to whether European safety standards are higher than those in the United States?

A. So as my opinion, I think that European standards differ from the U.S. I don't know that they're higher or lower.

If looking at -- I mean, if you look across the board at like genetically modified food, they don't allow that at all. The U.S. does. I don't know if one is better than the other, but they do have different regulatory bodies, which is -- you know, I was talking about earlier, right? I think that companies should be beholden to their government.

Q. You mentioned FDA standards and approval

Page 185

processes or clearance processes actually several times today. Would you agree that those are the minimum standard?

A. I don't know that I have an opinion on that. I think that there are standards in place that should be met. I think that if -- I guess if you don't meet those and you can't get to market and so I guess by definition, they would be a minimum.

Q. You would agree there's no requirement for a company to stop there and not warn of risk it knows about, correct?

A. I don't know that I understand the question.

Q. Sure.

A company could certainly meet the minimum standard to have a product to the market but also warn of the risk it knows about; couldn't it?

A. So a company can, yeah. It's possible.

Q. And you would agree as a practicing doctor, that would be optimal for a company to actually warn of the risks it knows about, correct?

MR. KOOPMANN: Objection.

Page 186

A. So, again, I don't -- I guess I don't know if you're suggesting that they report to the government body that provides approval or who it is that you are suggesting that they need to inform, right? Like --

BY MR. BRADFORD:

Q. More information is better, right?

MR. KOOPMANN: Objection.

A. I don't know that that's true to be honest. I think that as a physician, I want as much information as I could possibly get.

As a -- as a patient, it's hard to take in -- it's hard to drink from a firehose. It's hard to take in all possible information over the course of 30 minutes or 15 minutes.

So, you know, I think that pertinent information is important. I don't think it's possible to know everything, even for physicians, or for companies or for patients, so...

BY MR. BRADFORD:

Q. Would you agree that erosions are the most common risk with midurethral slings?

A. I don't think so. I think --

Q. What do you consider would be a more common risk?

Page 187

A. I think UTI is probably a higher risk than erosion.

Q. Would you agree that erosion is the second highest risk from midurethral slings?

A. So erosion risk, depending on what study you look at, is going to be somewhere between 1 to 3 percent in most studies. There are outlier studies that have higher rates than that, but many of the risks associated with any surgery are going to be kind of in that 3 to 5 percent range. So it is a risk. I don't know if it's the most common or second-most common. It's a known risk.

Q. And being either the most common or second-most common risk, do you agree that patients deserve to know what the company knows about that risk?

MR. KOOPMANN: Objection.

A. So, again, I think that -- again, perhaps it's a philosophical discussion, but based on how medicine is practiced in the United States, I think patients have conversations with their physicians to learn the information that's pertinent to them and their care. So, again, I don't know that a company can or should provide all information that it possibly can to

Page 188

physicians.

As we discussed, my day starts usually around 5:30 and ends around 10:00. I don't want constant communication or constant updates from a company that we did such and such study of five people and we have this outcome. Again, I would base things on high-level evidence, systematic reviews, level 1 evidence.

So, you know, is more information good? Yeah, but there's a point at which you can't get -- I mean, you can't have everything.

BY MR. BRADFORD:

Q. Well, certainly more information about one of the most common risks should be shared by the company; shouldn't it?

MR. KOOPMANN: Objection.

A. But, again, I would -- I guess I would counter it with, who are they sharing the information? Are they providing it to government organizations so that they are -- that the mandate or they cover the approval and the sale, and if they don't --

BY MR. BRADFORD:

Q. To doctors and patients.

A. So, again, as we've discussed, I think

Page 189

that physicians and patients get their information from different locations than from companies. I do.

Q. What is your opinion as to the erosion rate for the TVT?

A. So midurethral slings in general are going to be somewhere around 1 to 3 percent risk of erosion or exposure or whatever you want to call it.

Q. Sure. And so is that the same opinion you would have for the TVT retropubic?

A. In general, they're going to be pretty similar.

Q. Is that the same opinion for the TVT-O?

A. You know, again, for -- for midurethral sling mesh looking at systematic reviews, the rates quoted are usually somewhere around 2 percent, you know, plus or minus, so 1 to 3 percent.

Q. So it's your opinion that there's no difference or distinction from the erosion risk for the TVT, the TVT-O or the Abbrevo from the general midurethral sling population?

A. I think they share similar risk, yes.

Q. What mesh are you using for your

Page 190

abdominal sacrocolpopexy?
A. So I'm using the Coloplast Empathy. It's the Restorelle. Empathy was the prior company. It's Restorelle mesh. I use the Restorelle Y or the Restorelle M.
Q. And how long have you been using that mesh for your abdominal procedures?
A. When I came to New Mexico, they had transitioned and so I've used it since I came here.
In fellowship, I used a combination of Restorelle and the -- the -- I'm blanking on the name -- the Ethicon product, not the Prolene, but the Gynecare mesh. It was the Gynecare. I used that in fellowship and I used that in residency as well.
Q. The Gynecare PS?
A. Yes.
Q. What is the pore size for the Restorelle Y mesh that you're using?
A. The Restorelle Y is -- it's like 1800 microns.
Q. And what about for the Gynecare PS?
A. The Gynemesh is similar. I think it's somewhere around 2,000, but I'd have to double

Page 191

check that.
Q. What's the weight of the Restorelle Y mesh that you're using?
A. The Restorelle is like 18 -- I always forget the units -- 18 grams per meter square or something like that.
Q. I think that's right.
How about the weight of the Gynemesh PS?
A. And the Gynecare, I've looked at that as well and I don't remember. I know it's higher than that. The Restorelle is the lowest weight on the market. And some people think that's good. Some people think it's bad, but anyways, for the Gynecare, I don't remember offhand. 80 is in my brain, but that may not be right. It might be 80 grams per meter squared, but I'd have to look.
Q. Have you ever used Prolene for a sacrocolpopexy procedure?
A. In training, I did.
Q. When was that?
A. In residency and fellowship.
Q. When was the last time you used Prolene for the sacrocolpopexy?
A. It would have been back in the 2012-ish probably.

Page 192

Q. Why did you change to the Y mesh?
A. It's what they have at my institution.
Q. Does it work better?
A. I think that they're similar. Again, I haven't seen data that says that one is better than the other. There are risks and benefits to different meshes. Some people think the lightweight mesh might be better. Some people think the lighter weight mesh may lead to higher failure rates, and there's data to support one/or the other, but it's not conclusive.
Q. What do you think?
A. I think that if you know where you're putting the mesh and you know how to place it, I don't think it matters much.
Q. In your review of the Ethicon internal documents, did you see any documents referencing what Dr. Nilsson thought about mini slings?
A. Not that I recall. I'm sure that I saw it. I don't remember.
Q. Yeah, and Dr. Nilsson -- you're familiar with Dr. Nilsson, of course?
A. Yes.
Q. What's your understanding of who Dr. Nilsson is and what's significant about him

Page 193

regarding midurethral slings?
A. So I could be wrong. My recollection of Dr. Nilsson, I think they're -- I'd actually have to look. In my brain, they're a German surgeon, but I could be wrong. I'd have to look.
Q. All right. You cite Nilsson's reports and studies in your report on slings; is that correct?
A. Uh-huh.
Q. I was directing you to page 10.
A. Is this it?
Q. Yeah.
A. I have to look. Yep.
Q. All right. So does that jog your memory as to who Dr. Nilsson is?
A. So with -- with many of the references, I don't necessarily know them personally or who they are. So, you know, like if you were to ask me, you know, the details from a study, you know, I could certainly do that. If you're asking about him personally, I don't know Dr. Nilsson personally.
Q. Do you know what significance, if any, Dr. Nilsson had regarding the TVT sling?
A. I don't remember.

Page 194

Q. Okay. In your review of the Ethicon documents, did you come across anything referencing Dr. Nilsson's thoughts about mechanical cut mesh versus laser cut mesh?
A. You know, again, as we've discussed, I don't think there's much clinical significance between the two. And so I'm sure that I looked at the document because I looked through everything that I was sent. This was somewhere around a year ago. I do not remember the details.
Q. Okay. I'm going to ask my question again so we can get a direct answer to this.
Sitting here today, do you recall seeing anything in the internal Ethicon documents regarding what Dr. Nilsson thought about mechanically cut mesh versus laser cut mesh?
A. I do not recall.
Q. Sitting here today, do you have any memory -- strike that.
Do you know who Dr. Deleval is?
A. Again, I've heard of the name, and I don't know if Deleval is a he or she. They did the TVT-O similar to Delorme with the AMS Monarc. Delorme is a name I remember because they were kind of the first. Deleval is, I think, specific

Page 195

to Ethicon's product.
Q. In your review of Ethicon's internal documents, do you recall seeing anything about what about Dr. Deleval thought about mechanically cut mesh versus laser cut mesh?
A. Again, I've looked at the data for laser cut versus mechanical cut. It doesn't stick in my head because I don't think it matters.
So in reviewing the data, you know, I know that they did look at that as we discussed earlier. I'm sure that Ethicon had a reason for going from mechanically cut to laser cut. I don't remember all of those details.
Q. Okay. I'm going to ask it again.
Do you recall in your review of the Ethicon internal documents what thoughts, if any, Dr. Deleval had regarding mechanically cut mesh versus laser cut mesh?
A. I do not remember. I would have to refresh my memory.
Q. You reference ACOG and AUA and AUGS and SUFU in your report regarding midurethral slings.
Do you have an understanding whether or not their more recent position statements include mini slings as being acceptable devices?

Page 196

A. So the data on mini slings, most of the it is based on two devices. And so if you look at the Cochrane reviews in that, Steven Jeffries presented on that at AUGS a few years ago.
So the data on mini slings was not as promising, but I've heard that there may be newer mini slings that are more promising. In my personal practice, I don't use mini slings just based on the data. If that changes, I would consider using them. And to answer your question, I don't believe that ACOG or AUGS or IUGA or SGS or any of these have changed their position on midurethral slings.
Q. You state in your report on pages 13 into 14 that, "Polypropylene monofilament, large pore mesh is commonly accepted around the world as the best material available for midurethral slings."
Do you see that?
A. I agree with the statement, but I don't see where you're talking. It's on page 13.
Q. And carrying into 14. Sorry.
A. Yeah.
Q. Doctor, you're aware that in many parts of the world, midurethral synthetic slings are not allowed to be sold, right?

Page 197

A. I have heard that, yes.
Q. So that's not an accurate statement that it's commonly accepted around the world as the best material available for midurethral slings; is it?
A. Well, so I would say "commonly accepted around the world" means most places, not everywhere. And I think that it is still accepted as the best possible treatment option.
I know the UK did not allow the sale of them for a while. My understanding is that now they are back with restrictions as to who can place them, again, based on the data. But, you know, I'm referencing Ford's paper from 2017, which is a Cochrane review. So, you know, based on what Ford recorded in their Cochrane review, I would agree with their statement, but that is not to say that every single country everywhere offers it, but that may not be true.
Q. You reference in the bottom paragraph on page 14 in the section is your response to contentions by plaintiffs' experts --
A. Uh-huh.
Q. -- that -- I'm just going to read this. "Likewise, the extensive data supporting the

Page 198

safety and efficacy of midurethral slings does not support the theory that Prolene, polypropylene in the slings is cytotoxic or elicits an intense chronic foreign body reaction."

Do you see that?

A. Yes.

Q. Okay. Removing the qualifier "intense" away, would you agree that the Prolene mesh used in the TVT, the TVT-O and the Abbrevo does elicit a chronic foreign body reaction?

MR. KOOPMANN: Objection.

A. So, again, I think the question, at least for me, from my perspective, the question becomes a clinical question. If there was a lot of cytotoxicity, if there were problems caused by the mesh, the complication rates and the issues seen with the mesh would be much, much higher. The fact that, you know, the erosion rates I quoted were, you know, 1 to 3 percent, it would make me think that it's not -- that there may be a reaction to a foreign material, but it's not clinically important or clinically relevant.

In the pathology reports that I review when I take out mesh, they do comment on, you know, some inflammation around the mesh, but,

Page 199

again, from a microscopic view, if you're looking immediately adjacent to the mesh, if there's a foreign body, it wouldn't surprise me if there was some sort of reaction there, but it does not matter clinically because all these patients are not becoming eroded and extruded and getting infected and the rates are very low.

BY MR. BRADFORD:

Q. The people from whom the mesh is removed are certainly having complications from the mesh, be it erosions or pain or dyspareunia, correct?

MR. KOOPMANN: Objection.

A. So certainly there are patients who have problems or complications with any surgery. The same could be said for people with vaginal slings or Burch procedures. There are also complications or adverse events that can be associated and happen with those. But, again, I don't think you should throw the baby out with the bath water and say because there's a very, very low risk of complication, that no one should have the sling or that it shouldn't be on the marked because then you're discounting the 90-plus percent of women who have had significant improvement and significant benefit who now will be denied the

Page 200

opportunity for a very good treatment.

I certainly wish that there were no complications, but, again, there are no surgeries that don't. In the Schimpf article, which is also a reference to -- maybe it was on -- notes on this page as well, you know, their conclusion is the midurethral sling is the best option, and that's a systematic review and they compared it to Burch and pubovaginal slings.

BY MR. BRADFORD:

Q. I'll save my questioning for you on Schimpf in detail for another time --

A. Okay.

Q. -- and the flaws within Schimpf's analysis.

My question -- backing up -- was specifically regarding the chronic foreign body reaction. Let me ask it again.

You would agree that the Prolene polypropylene used in the TVT, the TVT-O and the Abbrevo elicit a chronic foreign body reaction?

A. So, again, I think any time a foreign body is implanted in the human body, there would be expected to be some sort of reaction to it. I do not think it clinically important.

Page 201

Q. You would agree that reaction for the midurethral slings is a chronic foreign body reaction?

A. As we discussed earlier, the midurethral sling is meant to be permanent. It does not dissolve and go away. So, you know, it's a chronic device.

Q. Are you familiar with Vypro?

A. I've heard of Vypro. It's the mesh that I believe has Vicryl strands that dissolve and go away.

Q. Are you familiar with Ultrapro?

A. It's similar.

Q. Do you have any understanding as to why Ethicon developed Vypro and Ultrapro?

A. There were theories -- as we've discussed with the Restorelle mesh, there were some theories that perhaps less mesh is better than more mesh.

Q. Do you agree with that?

A. Again, I would base things based on the data. There's not a lot of data to support the quote/unquote lighter weight meshes. If there's data to show that they are as effective with a better safety profile, then I would say they should be used. Until such time as that can be

Page 202

demonstrated, I would stick with what is tried and true, so...
Q. You would agree that the Burch procedure and pubovaginal slings in native tissue repair was tried and true before Ethicon decided to use hernia mesh in the pelvic floor; wouldn't you?
A. So what I would say is the Burch was first described back in the '60s. Pubovaginal sling, I think was in the '60s or '70s, but I don't remember exact, I think, '70s, '74 is in my brain.
What I would say is if it was as effective, it would still be considered the gold standard and the midurethral sling would not have taken off to the extent that it has. Burches are a much more invasive procedure than a midurethral sling; so are pubovaginal slings. And, again, when looking at the data, the midurethral sling performs better. So, again, I am a proponent of things being done safely, but I am also a proponent of medical progress. And I sure hope that in 2050, we are not practicing exactly the same way we are in 2020 because I hope we've made progress in that time.
So, you know, to go back and say that the

Page 203

midurethral sling should never have been developed because there was an option, I don't think is an accurate statement.
Q. That's a good point.
You would agree that there are advances in medicine generally as time goes on, correct?
A. That has been the case and I hope that that continues.
Q. And you would agree that there have been advances in polypropylene compositions for meshes used in the human body, correct?
A. I don't know if that is true. The polypropylene mesh Prolene suture was first sold back in like the -- like in '54, quite a while ago, 60 years ago. And, again, I have not delved -- delved, is that a word -- I have not gotten into the chemical composition of all the different variations of Prolene, but essentially, Prolene suture is what was used in Prolene mesh.
Q. Let me ask a better question.
Specifically as to woven polypropylene synthetic meshes, okay --
A. Okay.
Q. -- you would agree that there have been developments over the past 20 years in woven

Page 204

polypropylene synthetic meshes; wouldn't you?
MR. KOOPMANN: Objection.
A. So I think that there are different ways. There are knits. There are weaves. There are different substances, you know, aside from Prolene that have been used in meshes and so, yes, there have been variations and options.
BY MR. BRADFORD:
Q. You would agree that it would not be proper for a company to not change its mesh because it would lose the studies and the data it had for previous mesh?
MR. KOOPMANN: Objection.
A. So, you know, again, going back to the prior line of questioning, you know, I think that, unfortunately, in medicine, there are no way to make advancements without doing studies. So, you know, on the one hand, you know, we shouldn't have developed a mesh because we had the Burch and the pubovaginal sling, but on the other hand, we should throw out all the data on the mesh in -- to replace it with a different mesh.
I think that, you know, if data emerges and if things progress and we find that there's a different mesh that is more suitable with a better

Page 205

risk/benefit profile, then, yes, we should convert to that. Until such time, the risk/benefit profile for the current meshes available are quite good, which is why people aren't jumping to get away from them.
BY MR. BRADFORD:
Q. In your review of Ethicon's internal documents, did you see anything that referenced Ethicon's desire not to change the Prolene mesh used in the TVT because it had all those years of data and it didn't want to lose that. Did you see that?
A. I don't recall that, but it would make sense to me. And as an aside, you know, I'm surprised that someone hasn't purchased AMS's Monarc because there are years and years of data. It's one of the most studied products that was on the market that's been -- the company just stopped making it. So, you know, it wouldn't surprise me if a company has something that has a good safety profile, a good risk/benefit profile to not want to go away from that. That would make sense, but I don't remember seeing that specific communication.
BY MR. BRADFORD:

Page 206

Q. If there's a safer mesh available for midurethral slings, Ethicon should use it; shouldn't they? Let me ask a better question, sorry.

If there is a safer mesh that has the same or similar efficacy for its midurethral slings, Ethicon should use that mesh; shouldn't it?

A. So, again, if we're talking hypothetical or theoretic, yes, if you can find something that is a safer and better, but I think that if you have something that is already safe and good, you need to demonstrate similar efficacy and similar safety before you jump to said product.

Q. You reference in your report on page 16 that it is, quote, "Pure speculation or conjecture to purport or state that mesh slings with larger pore sizes or lighter weight mesh than the typical type 1 polypropylene mesh would have been safer or more effective."

Do you see that?

A. Yep, I see it.

Q. You would agree there in internal Ethicon documents that show the company knew the larger pored, lighter weight mesh was safer; don't you?

Page 207

A. I don't know that I would agree with that.

I would say, again, when I'm making my medical decisions, I'm basing it on primarily level 1 evidence. There is a lot of good evidence supporting the use of midurethral slings. I have not seen in published research studies or published data that show that a larger pore mesh is safer or more effective. So, you know, again, if they have internal documents that show that, then they should continue to do studies and bring it to market. Until such time, I think that what we have is what is should be used.

Q. You would agree that the IFU for the TVT, the TVT-O and the TVT Abbrevo state that Prolene mesh elicits a minimal inflammatory reaction in tissue based on animal studies, correct?

A. That rings a bell. That sounds right. I'd have to look at the IFU, but I believe that to be the case.

Q. Right. And the IFU goes on further to say that, "The reaction is transient," correct?

A. So, again, as we had discussed earlier, any time a surgery is performed, there are healing factors and healing issues related to the

Page 208

immediacy after surgery and then longer term. So, you know, I think that as far as, you know, transient, there's a transient healing period after any surgery that is transient and patients heel.

You know, we've talked earlier about the chronic nature of the implanted device. The device is permanent. It is meant to stay in place for a long -- for -- really for life. It's not intended to be removed. So as such, there is a transient healing, but then there's a chronic device in place.

Q. What's "transient" mean to you?

A. "Transient" to me means something that would last for a certain period of time and then pass.

Q. And it's your opinion that Prolene mesh elicits a minimal inflammatory reaction?

A. My clinical experience is that, yes, it does elicit a minimally inflammatory response. There's not a lot of inflammation around mesh. Even when you go in and take it out, there's not all this like grossly evident irritation inflammation.

Q. Is it your opinion that that reaction is

Page 209

transient in the TVT, TVT-O and Abbrevo?

A. Again, during the healing process, the healing process is a transient period.

THE COURT REPORTER: I think I need five minutes.

MR. BRADFORD: Sure.

(Whereupon, a brief recess is taken from 2:36 p.m. to 2:43 p.m.)

BY MR. BRADFORD:

Q. All right, Doctor, we're getting there.

You've got some opinions regarding general sacrocolpopexy for prolapse, correct?

A. Yes, sir.

Q. All right. I don't want to get a whole lot deep into that. I've asked some questions a little bit about it already, but you agree that the procedure itself is better to repair prolapse abdominally than vaginally; wouldn't you?

A. I think it depends on the patient, their age and the degree or stage of prolapse.

Q. Tell me more about that.

A. So I think that the medical literature supports the safety and efficacy of sacrocolpopexy. There are Cochrane reviews and other systematic reviews that consider it the gold

Page 210

standard, and many providers think it's the gold standard. I think it's a very good option. I also think that vaginal surgeries can be good options for certain patients.

The long-term success rates of sacrocolpopexy are better. It's a more durable procedure, but there are different risks associated with the different procedures.

Q. Would you agree that if the doctor decides to use Prolene mesh in a sacrocolpopexy procedure, that's the same Prolene mesh that's used in the TVT and the TVT-O and the Abbrevo, correct?

A. Again, it's the type 1 polypropylene mesh. The chemical composition, it's very similar, if not in the same, but I'd have to look.

Q. Right. And I'm -- essentially Prolene is Prolene, right?

A. So polypropylene, you know, in general, they are similar. It does depend on if it's knitted or woven or pore size, you know, that kind of stuff does come into play. So, yeah, you can't blanketly say that they're always the same, but type 1 polypropylene mesh, they should be similar.

Q. If a surgeon uses Prolene mesh, the

Page 211

Ethicon Prolene mesh for an abdominal procedure for prolapse, that's a different cut and a different size, but it's the same core mesh that's used in the TVT, correct?

A. Again, my understanding is they are very similar.

Q. I'm going to ask you about degradation. We talked -- we kind of bounced -- touched on it, but I want to ask you some questions about degradation for the Prolene mesh.

Do you agree that Prolene mesh degrades in the body?

A. So I don't think that it does degrade in the body.

Q. Have you seen any internal Ethicon documents that are contrary to your opinion?

A. I have.

Q. And have you seen any Ethicon witness -- corporate witness depositions that are contrary to your opinion?

A. Yeah, there are some contrarian views. Based on clinical experience and based on overall published literature, it is intended to be a permanently-implanted device, but I don't go back later and find mesh that needs to be removed and

Page 212

take it out and find that it's disintegrating and falling apart. It has very similar properties when removed as though it did when it was placed.

Q. Let me ask you some questions about mesh contraction.

You would agree that the Prolene mesh contracts when implanted in the body?

A. So in the literature that I have reviewed and data that I reviewed from studying for my boards, you know, it's about 10 percent over the first year.

Q. In your review of Ethicon internal documents, did you come across any that find a higher rate of contraction than 10 percent?

A. So there are reports, I think some that go up to 30 percent.

Again, based on clinical experience and having implanted many, many different sacrocolpopexy meshes and followed patients over a long period of time and seen patients back by my partners who have treated them many, many years ago, there is not significant clinical contracture. So, you know, if mesh were contracting by 50 percent, you'd expect to see significantly higher complication rates, which we

Page 213

don't see.

Q. So in your practice, you've not seen that clinically, correct?

A. Clarify what? What do you mean I haven't seen?

Q. Thank you.

In your practice, it's your testimony that you have not seen contraction rates or contraction amounts of more than 10 percent, correct?

A. So, you know, again, it's a proportion, but based on my clinical experience, I would say that it's in line with the literature that I've a seen that quotes somewhere around 10 percent.

Q. I believe your reliance list indicates you reviewed the work and deposition of Drs. Klinge and Klosterhalfen.

Do you recall what they said about mesh degradation and contraction?

A. I'd have to review it to refresh my memory.

Q. Sitting here today, do you know how Dr. Klinge is?

A. I've heard the name, but I don't recall details.

Page 214

Q. Sitting here today, do you know who Dr. Klosterhalfen is?
A. So I don't remember for sure. I -- I could take a guess, but I don't remember exactly who Dr. Klosterhalfen is; a German surgeon maybe. I think that sounds more like her name, but I don't remember.
Q. I hate to do this just after the other break, but I'm going to take a step out and go through some notes. I think I'm about done.
MR. KOOPMANN: Sure.
(Whereupon, a brief recess is taken from 2:50 p.m. to 2:59 p.m.)
BY MR. BRADFORD:
Q. Doctor, I'm going to ask some questions about Exhibit T-10.
A. Okay.
Q. That's your CV, correct?
A. Yes, sir.
Q. All right. And on there you listed a lot of things. I want to go through a couple to make sure I've got a thorough understanding of certain parts.
On page -- I'm sorry. The pages aren't numbered, but on the portion under, "Invited

Page 215

Lectures" --
A. Yep.
Q. Let me tell you what I've done. I've looked through it to try to identify what has to do with stress urinary incontinence, midurethral slings or other treatments for stress urinary incontinence, okay?
A. Okay.
Q. And under, "Invited Lectures," I see the, "November 2014, Cadaveric Lab Presentation," you did in Vancouver, correct?
A. Yes.
Q. That's the only one I see for your invited lectures that has anything to do with stress urinary incontinence, synthetic meshes or nonsynthetic meshes or surgical or nonsurgical treatment of SUI. Am I missing any?
A. No.
Q. All right. I want to next talk about the publications that are peer reviewed.
A. Okay.
Q. The first one you're listed as an author and a string of others, correct?
A. I'm listed as -- I'm an author or coauthor of all of these.

Page 216

Q. Correct.
And that one is regarding pelvic organ prolapse surgery, correct?
A. Which one?
Q. The first one.
A. Oh, No. 1?
Q. Yes, sir.
A. Yes.
Q. And the second one involves prolapse severity, correct?
A. Yep.
Q. Okay. And as you look through this with me, I'm looking for prolapse, SUI, treatment, meshes, non-meshes, nonsurgical, surgical whatever, okay?
A. Okay.
Q. Just to be sure I'm not missing any, there's No. 1, No. 2, No. 22? Take your time. I'm not trying to rush you.
A. Yeah.
Q. On the page you're looking at now, Doctor, I have No. 22 marked?
A. Yep.
Q. We've talked a bit about that study; haven't we?

Page 217

A. We have.
Q. And I have No. 29 marked.
A. Okay.
Q. Any others on that page involving the topics that we -- that I mentioned just earlier?
A. So you said 21. 21 is prolapse. 22 is sling. 23 is prolapse.
Q. 26 is prolapse also? I think I looked at this for slings actually.
A. Okay. 29 is sling.
Q. Any others?
A. I don't know. There are -- maybe they're not. I thought I put them on. I have -- but I don't see them, but they're treatment of urinary incontinence, but there is Annals of Internal Medicine that has been published recently and another -- those are all on urinary incontinence, but they're not surgical. I don't know if that matters.
Q. It does. No, I'm curious about them.
MR. BRADFORD: Can you get them to me?
MR. KOOPMANN: Yeah.
A. I don't know if -- I always keep my CV updated. I'm surprised that they're not here.
MR. KOOPMANN: I can get you an updated

Page 218

CV once he adds those.
MR. BRADFORD: Sure.
A. I don't know where they went though. That's the weird thing. They should be on here. Yeah, there's -- there are three more. One is a PCORI/NIH funded study about nonsurgical treatment of SUI -- of UI, just in general.
BY MR. BRADFORD:
Q. That is on here.
A. Is that on here somewhere? It should be under, "Publications," though. That would be listed as a funding source, but the study is done and published and so it should be somewhere right around 7 and it's not.
MR. KOOPMANN: Is it in the CV that's been included in the binders?
THE WITNESS: Oh, maybe. It might be in the updated one. Let me see. No, this is the same one. I must -- it must have been omitted. Those are abstracts. Yeah, it's -- so this is an outdated CV. So 9 and 10 and 13 are nonsurgical treatments of urinary incontinence in women.
So one is an update for the AHRQ and PCORI. It's an NIH funding organization. That was published in August of 2018.

Page 219

And then No. 9 is, "Adverse events associated with nonsurgical treatments of urinary incontinence in women; a systematic review." That was accepted to the Journal of General Internal Medicine. And then there's a, "Nonsurgical treatment for urinary incontinence in women; systematic review and network metaanalysis," and that was in the Annals of Internal Medicine.
So I think those are pertinent, but this is my most recent. I'm not sure how old this CV is, March of '18. So this CV is a year old. This one is my recent.
BY MR. BRADFORD:
Q. It's dated April 12th of '19?
A. Yeah.
Q. So we have that so there's no reason to mark it separately?
A. Correct, it's already marked.
Q. And then regarding the grants, we mentioned the AHRQ grant for, "Nonsurgical treatments for urinary incontinence in adult women," correct?
A. Yep.
Q. And then on No. 4, there's an NIH grant regarding pelvic floor disorders.

Page 220

Did that carry over into some of the issues that you're giving opinions about today?
A. I don't think so.
Q. It didn't read like it would, but I wanted to double check.
A. Yeah, I'm not speaking for -- for them.
Q. Great.
A. That's what these studies came from. Nos. 1 and 2 were PFDN studies.
Q. Under your abstracts, I want to ask you about No. 21.
A. Okay.
Q. Okay. What do you remember, if anything, about that post or presentation?
A. So that post or presentation became the publication that you asked me about earlier.
Q. Thank you.
A. It's just the same project. Typically with research, you get results. You submit to a meeting, present at the meeting and then go on to publication.
Q. Thank you, Doctor.
And then on No. 28?
A. Yep.
Q. Okay. It's -- what do you recall, if

Page 221

anything, about that oral presentation?
A. I can remember everything about it. Do you want me to tell you about it?
It was also published, but that was published in Obstetrics and Gynecology. So if you go to my publication list, it will be No. 29.
Q. Let me ask a couple of questions about it.
We did a search of you and that actually showed up in Ethicon's database and the -- and I found it actually way, way too early this morning and it -- do you recall on the schedule, it was under a session titled Tips and Tricks. Do you recall that?
A. Yeah, it was at SGS.
Q. And what are Tips and Tricks?
A. So different medical societies have -- their meetings are planned different ways. Tip and Trick could be more like a way to handle something maybe in a new or novel way or something different than has been described before.
Q. Right. Sometimes that can be different from what's in the IFU, for example?
A. Potentially, yeah.
Q. All right. And do you recall how long

Page 222

that presentation was?
A. I don't recall, five minutes, five to eight minutes would be my guess.
Q. That's about what I thought too. We can put the CV away. Put the binder back up too before I lose it.
Dr. Jeppson, these slings that you've talked about today, they are identified as being tension-free, correct?
A. Yes.
Q. Would you agree that they're not truly tension-free?
A. I think it depends on how you define "tension." When I place them and when I teach the fellows and residents how to place them, we do want them to be tension-free or not tight, I guess would be the synonym. If they're too tight, they tend to be obstructive and patients have a hard time voiding. So you want it quote/unquote tight enough that they don't leak but not so tight that they can't pee.
Q. So is it fair to say you want them tensioned enough that they work but not so tensioned that it causes obstruction or other problems?

Page 223

A. I think that is what I'm saying, but, you know, I think that is tension-free. They should just kind of sit underneath the urethra. They should be at the midurethra.
Q. Doctor, do you agree that in certain patients the midurethral slings that we've talked about today can cause nerve entrapment?
A. So I think there can be neurogenic pain issues. When I think of a nerve entrapment, I think of actually placing a suture or something around a nerve to -- to wrap around and entrap it.
Based on the anatomy, there are, of course, nerves everywhere in the body and in the pelvis, but there's not a discrete nerve that would be wrapped around. It's not like when you do a laparoscopy in closed in port sites, you can close the ilioinguinal or hypogastric nerves and it's things like that that would cause quite a bit of pain. There's not a discreet nerve like that. These would be branches of the pudendal nerve, which comes in from the lateral side walls and migrates medially.
Q. So there can be branches of nerves that might be entrapped or encapsulated in mesh in certain patients?

Page 224

A. So, you know, any time anyone has surgery, there is a risk of, you know, abdominal incisions, everything. There are nerves in the area because there are nerves for sensation in the body. I don't know that I would expect them to be encapsulated or entrapped. They are probably severed or interrupted as the mesh passes, but, again, the mesh burden or the mesh diameter is so small that the -- it does not effect any major nerves. It shouldn't effect major nerves.
Q. Would you agree that the contraction process can affect the nerves of the pelvic floor?
A. So, you know, again, as we've discussed, you know, I think mesh does contract to a certain extent during the healing phase and after implantation. We've discussed that the pain is a known risk factor of mesh insertion and mesh placement. Could some of that be due to the slight contraction? Possibly. Could it be due to the surgical implantation? Possibly. You know, again, these risks are present with pubovaginal slings, which are placed in a very similar location and different nerve issues could be found with Burch surgeries, which are placed in, you know, a different location but still would

Page 225

traverse the abdominal wall and pelvis.
Q. Would you agree that if the pore size is too small for a synthetic mesh, it can increase the risk of infection, erosions and exposures?
MR. KOOPMANN: Objection. Go ahead.
A. So that has been demonstrated by the Amid and subsequent papers and, you know, there's quite a bit of literature around that. Again, I think it depends on how you define, you know, quote/unquote, too small. But in general, a type 1 mesh is greater than 75 microns.
BY MR. BRADFORD:
Q. Would you agree that in general a less stiff mesh is better?
A. So, you know, again, stiffness is somewhat relative. From the perspective of, you know, physiologic range in the human body, you know, I don't know that there's a whole lot of difference in the different types of meshes that we were discussing. You know, the perfect mesh would be just the right stiffness, not too stiff, not to lacks. But, again, you know, I don't know how you're defining "stiff." Meshes are inherently stiffer than the human body, which is why they're used because the human body is having

Page 226

issues with leaking and prolapse.
Q. You would agree that meshes closer to replicating the tissue within the pelvis or pelvic floor is better than overly-stiff mesh?
MR. KOOPMANN: Objection.
A. So, again, I think that when we're talking about mesh and what's been published on mesh, I would defer to the medical literature as to, you know, what is the best.
You know, mesh has been shown to be better than biologics, certainly for slings and for sacrocolpopexy. So, you know, again, it needs to be stiff enough. You don't want it to be too stiff, but it all depends on how you define "stiff" and what stiffness is.
BY MR. BRADFORD:
Q. I think I've been through this, but briefly, you've never helped a company get a product through the 510(k) process; have you?
A. So the 510(k) process for meshes was replaced by the 522 process. Some of the organizations have collected data for those types of things. I have been involved in studies through the PFDN, looking specifically at pelvic mesh that I think will be used for their 522

Page 227

processes. Part of the FDA mandate that came out on April 16th or 15th, whenever that was, is that the companies need to continue those studies and continue to follow patients. So I have not been paid by the companies to perform those studies or to report on them, but I have been involved in studies that will be used by companies for their products, so...
Q. You haven't been hired in this case to serve as an expert regarding the FDA; have you?
MR. BRADFORD: Counsel, can you help us on this one?
MR. KOOPMANN: I will stipulate that he is not being disclosed as an FDA regulatory expert.
BY MR. BRADFORD:
Q. And you're not an expert regarding the PMA approval or clearance process; are you?
A. So, again, I would defer to the regulatory bodies regarding those.
MR. BRADFORD: Thank you, Doctor. Those are all the questions I have. I appreciate your time.
THE WITNESS: Thank you.
EXAMINATION BY MR. KOOPMANN:

Page 228

Q. Just some brief followup and, again, reminder to try to direct your answers to the court reporter since I'm sitting next to you.
And just for the record, my name is Barry Koopmann and I represent Ethicon and Johnson & Johnson and I have some follow-up questions for you, Dr. Jeppson, okay?
A. Okay.
Q. Just so I'm clear, did you review more medical literature than the medical literature that has been included in these binders today?
A. Yes.
Q. Have you also in the course of your work in the pelvic mesh litigation over the past year or so reviewed several plaintiffs' experts' reports?
A. Yes.
Q. And do some of those plaintiffs' experts' reports that you've read reference internal Ethicon or Johnson & Johnson company documents?
A. Yes, they do.
Q. And did those reports sometimes paraphrase and or even quote those internal company documents?
A. Yes.

Page 229

Q. And you've reviewed those reports in the course of forming your opinions in this case; is that true?
A. Yes.
Q. When you have a patient referred to you to treat a complication after a pelvic surgery, whether it's mesh or non-mesh and you didn't perform the initial surgery that was done to treat that patient's incontinence or prolapse, do you try to get the medical records from that initial surgery done by some other surgeon if you're thinking about removing some portion of the mesh from that patient?
A. Yes. I would always prefer to know what was placed and how it was placed. It's not always possible, but I would prefer that.
Q. One of the -- you were asked some questions earlier about studies that you've looked at that compare laser cut mesh versus mechanically cut mesh. Do you remember those questions generally?
A. Yes.
Q. In your midurethral sling general report, did you cite a study by an author, lead author named Rusavy titled, "Are the same tapes really

Page 230

the same? Ultrasound study of laser cut and mechanically cut TVT-O postoperative behavior"?
A. Yes.
Q. And what's your recollection of what that study showed with respect to laser cut versus mechanically cut slings?
A. So I would have to review it for the full details, but my general recollection is that there is a difference between the two, but it doesn't seem to be clinically important.
Q. Do the systematic reviews and metaanalyses that you've relied on in the course of forming your opinions in this case, do those look at all of the available information that meets the authors' inclusion criteria regardless of whether it's favorable or not favorable regarding the device?
MR. BRADFORD: Form.
A. I'm sorry. Could you repeat the question?
BY MR. KOOPMANN:
Q. Sure. Do the systematic reviews and metaanalyses that you've relied on, looked at, for the purpose of forming your opinions in this case, do those look at all of the available information

Page 231

that meets the authors' inclusion criteria regardless of whether it's favorable or not favorable regarding the device?
MR. BRADFORD: Form.
A. Yes, yes. That is how systematic reviews are designed.
BY MR. KOOPMANN:
Q. You were asked some questions earlier about sort of a hypothetical situation where if there's a mesh with similar efficacy -- if there are two meshes with similar efficacy, should the company use the mesh that has -- that is safer? Do you remember those questions generally?
A. Yes.
Q. Could one study show that one mesh is safer than the mesh that's used in the TVT, TVT-O or TVT Abbrevo mesh in your opinion at this point?
MR. BRADFORD: Form.
A. So I think that composite knowledge is what is important for medical care. And so I would not base, you know, my foundation of knowledge on one study but rather the composite information from a multitude of studies, preferably high-quality studies such as randomized controlled trials or systematic reviews as I've

Page 232

discussed previously.
BY MR. KOOPMANN:
Q. Could one company e-mail indicating that one mesh is safer than the mesh in the TVT, TVT-O or TVT Abbrevo establish for you that that mesh is safer than the TVT, TVT-O or TVT Abbrevo mesh?
MR. BRADFORD: Form.
A. No. That would represent one person's opinion and may be interesting but would not overly sway the large body of evidence.
BY MR. KOOPMANN:
Q. Do your general reports regarding the TVT, TVT-O and TVT Abbrevo and your report regarding the Prolene mesh and Gynemesh PS as used in sacrocolpopexy procedures, do they contain your opinions regarding the safety and efficacy of those mesh products?
A. Yes.
Q. And do you hold the opinions that you set forth in your general reports that have been marked as exhibits today to a reasonable degree of medical certainty?
A. Yes.
Q. And do you hold the opinions that you've offered today in this deposition to a reasonable

Page 233

degree of medical certainty?
A. Yes.
Q. Generally speaking, what are the bases for the opinions that you've offered here today in terms of your background information?
A. So as previously discussed, you know, my medical knowledge is based on a composite of life experience, patient treatment, review of medical literature, medical school learning, residency and fellowship, as well as, you know, textbook reading and keeping up with the literature in general. So it's the composite of experience and knowledge.
Q. Would it also be based in part on discussions that you've had with colleagues within the urogynecologic community?
A. Yes.
MR. BRADFORD: Form.
A. Yes.
BY MR. KOOPMANN:
Q. Do you practice evidence-based medicine?
MR. BRADFORD: Form.
A. I try to practice evidence-based medicine.
BY MR. KOOPMANN:
Q. What does "evidence-based medicine" mean?

Page 234

A. "Evidence-based medicine" means that essentially there is a -- it's not a moving target, but it's a continuously progressing target where if you practice medicine based on the evidence of today, you will probably be out of date by, you know, the year 2030. So evidence-based medicine means keeping up with publications, keeping up with the medical literature, keeping up with the experiences of others, as well as myself, and modifying practice based on new innovations and new publications as they come out.

Q. Within the practice of evidence-based medicine, is some evidence thought of as being more powerful than other evidence?

A. Yes.

Q. What are the highest levels of evidence within the practice of evidence-based medicine?

A. So in general, the highest level of evidence would be considered systematic reviews and metaanalyses. Cochrane reviews are a form of systematic review. It only includes randomized controlled trials. Sometimes there are advantages for that. Sometimes there are disadvantages for that, but in general, randomized -- in general,

Page 235

systematic reviews are going to be the highest.

Randomized controlled trials are also a very good form of evidence, a very high-level, level 1 evidence. Beyond that, there are, you know, comparative cohort studies, case control, case series, you know, and expert opinion would probably be down at the bottom.

Q. Where do internal company e-mails, documents or PowerPoint presentations fall within that hierarchy?

MR. BRADFORD: Form.

A. They don't. They are not on the list.

BY MR. KOOPMANN:

Q. Are levels of evidence important in assessing the safety and efficacy of the devices that you've written your reports about?

A. Yes. My opinions are based on level 1 evidence essentially.

Q. Are Cochrane reviews, randomized controlled trials and systematic reviews and metaanalyses, in your opinion, reliable in determining the safety and efficacy of the devices that you've written reports about?

MR. BRADFORD: Form.

A. Yes.

Page 236

BY MR. KOOPMANN:

Q. And why is that?

A. Again, as we discussed, it's the highest level of evidence. So the level 1 evidence would be better than, you know, some case series or case report of one patient where something unfortunate happened.

Ideally, you know, the medical opinions and the practice of medicine should be based on high-level evidence.

Q. And what sort of evidence did you focus on in your research done to form the opinions that you've expressed here today in the deposition and in your general reports?

A. So as much as possible, level 1 evidence.

Q. Are the complications that you've seen in your practice with the use of the TVT, TVT-O and TVT Abbrevo devices and the Prolene mesh and Gynemesh PS consistent with the warnings listed in the adverse reactions section of those products' IFUs?

MR. BRADFORD: Form.

A. Yes.

MR. KOOPMANN: All right. Those are all the questions I have for you. Thank you,

Page 237

Dr. Jeppson.

THE WITNESS: Thank you.

MR. BRADFORD: Bear with me one second. I don't have any questions.

MR. KOOPMANN: We'll read and sign.

(Time noted: 3:29 p.m.)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
MASTER FILE NO: 2:12-MD-02327

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION MDL 2327

CERTIFICATE OF COMPLETION OF DEPOSITION

I, DANA N. SREBRENICK, RPR, CLR, CRR, NM CCR #513, DO HEREBY CERTIFY that on Thursday, May 16, 2019, the Deposition of PETER JEPPSON, MD, FACOG, FACS was taken before me at the request of, and sealed original thereof retained by:

BRAD BRADFORD, ESQ.
ATTORNEY FOR PLAINTIFFS
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
17 East Main Street, Suite 200
Pensacola, Florida 32502

I FURTHER CERTIFY that copies of this Certificate have been mailed or delivered to all Counsel, and parties to the proceedings not represented by counsel, appearing at the taking of the Deposition.

I FURTHER CERTIFY that examination of this transcript and signature of the witness was requested by the witness and all parties present.

On _____, 2019, a letter was mailed or delivered to BARRY J. KOOPMANN, ESQ., regarding obtaining signature of the witness, and corrections, if any, were appended to the original and each copy of the Deposition.

I FURTHER CERTIFY that the recoverable cost of the original and one copy of the Deposition, including exhibits, to BRAD BRADFORD, ESQ., is $_____.

I FURTHER CERTIFY that I did administer the oath to the witness herein prior to the taking of this

stenographic shorthand the questions and answers set forth herein, and the foregoing is a true and correct transcript of the proceeding had upon the taking of this Deposition to the best of my ability.

I FURTHER CERTIFY that I am neither employed by nor related to nor contracted with (unless excepted by the rules) any of the parties or attorneys in this case, and that I have no interest whatsoever in the final disposition of this case in any court.

_____
DANA N. SREBRENICK, CRR, CLR
NM CCR #513
License Expires: 12/31/2019

ERRATA

PAGE	LINE	CHANGE
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		
____	____	_____
REASON: _____		

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
[WITNESS NAME] DATE

Subscribed and sworn to
before me on this _____day
of_____,20___, by _____
_____,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____